VS-800

Vital signs monitor

Service Manual

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Mindray is responsible for safety, reliability and performance of this equipment only in the condition that:

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- applied electrical appliance is in compliance with relevant National Standards;
- the monitor is operated under strict observance of this manual.

⚠ Warning ⚠

For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

- **Do not rely only on audible alarm system to monitor patient. When monitoring adjusting the volume to very low or completely muting the sound may result in the disaster to the patient. The most reliable way of monitoring the patient is at the same time of using monitoring equipment correctly, manual monitoring should be carried out.**
- **This vital signs monitor is intended for use only by medical professionals in health care institutions.**
- **To avoid electrical shock, you shall not open any cover by yourself. Service must be carried out by qualified personnel.**
- **Use of this device may affect ultrasonic imaging system in the presence of the interfering signal on the screen of ultrasonic imaging system. Keep the distance between the monitor and the ultrasonic imaging system as far as possible.**
- **It is dangerous to expose electrical contact or applicant coupler to normal saline, other liquid or conductive adhesive. Electrical contact and coupler such as cable connector, power supply and parameter module socket-inlet and frame must be kept clean and dry. Once being polluted by liquid, they must be thoroughly dried. If to further remove the pollution, please contact your biomedical department or Mindray.**

It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

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- The VS-800 is not used in accordance with the instructions for use, or the electrical installation of the relevant room does not comply with NFPA 70: National Electric Code or NFPA 99: Standard for Health Care Facilities (Outside the United States, the relevant room must comply with all electrical installation regulations mandated by the local and regional bodies of government).

Return Policy

Return Procedure

In the event that it becomes necessary to return a unit to Mindray, the following procedure should be followed:

1. Obtain return authorization. Contact the Mindray Service Department and obtain a Customer Service Authorization (Mindray) number. The Mindray number must appear on the outside of the shipping container. Return shipments will not be accepted if the Mindray number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.

2. Freight policy. The customer is responsible for freight charges when equipment is shipped to Mindray for service (this includes customs charges).

Company Contact

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Phone: +86 755 26582888

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Safety Precautions

1 . Meaning of Signal Words

In this manual, the signal words **DANGER**, **WARNING**, and **CAUTION** are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
⚠**DANGER**	**Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.**
⚠**WARNING**	**Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.**
⚠**CAUTION**	**Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.**
CAUTION	**Indicates a potentially hazardous situation which, if not avoided, may result in property damage.**

2 . Meaning of Safety Symbols

Symbol	Description
	Type-BF applied part
	"Attention" (Refer to the operation manual.)

3 . Safety Precautions

Please observe the following precautions to ensure the safety of service engineers as well as operators when using this system.

⚠**DANGER:**	**Do not use flammable gasses such as anesthetics, or flammable liquids such as ethanol, near this product, because there is danger of explosion.**

⚠WARNING: **Do not connect this system to outlets with the same circuit breakers and fuses that control current to devices such as life-support systems. If this system malfunctions and generates an overcurrent, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building's supply circuit may be tripped.**

⚠CAUTION:

1. **Malfunctions due to radio waves**

   (1) Use of radio-wave-emitting devices in the proximity of this kind of medical electronic system may interfere with its operation. Do not bring or use devices which generate radio waves, such as cellular telephones, transceivers, and radio controlled toys, in the room where the system is installed.

   (2) If a user brings a device which generates radio waves near the system, they must be instructed to immediately turn OFF the device. This is necessary to ensure the proper operation of the system.

2. **Do not allow fluids such as water to contact the system or peripheral devices. Electric shock may result.**

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For your notes

Chapter 1 Monitor Description

1.1 Intended Use

The VS-800 Vital Signs Monitor is intended to monitor the vital signs of single patients. It applies to the health-care institutions such as Outpatient Clinics, Emergency Departments, Medical Floors, Clinics, Nursing Departments and so forth. The VS-800 is employed by qualified personnel according to the evaluation of the patient's health conditions.

- Applied to: adult, pediatric and neonate
- Monitored parameters:
  - PR (obtained based on the SpO_2 or NIBP data)
  - NIBP (systolic pressure, diastolic pressure and mean pressure. Oscillometry NIBP)
  - SpO_2 (SpO_2: Pulse Oxygen Saturation)

This product is to be employed by qualified health-care personnel who have been trained on the product. It supports continuous monitoring. It, however, is not intended to monitor critical patients and those in transportation (ambulance).

1.2 Environmental Specifications

1.2.1 Temperature Requirements

Operating ambient temperature	0℃ - 40℃
Storage temperature	-20℃ - 60℃

1.2.2 Relative Humidity

Operating relative humidity	15%-95%(non-condensing)
Storage relative humidity	10%-95%(non-condensing)

1.2.3 Altitude Requirements

Operating altitude	-1,640 - 15,092 feet (-500 - 4,600m) Note: Requirements for the optional Nellcor® Oximax® SpO2 (NELL-3):

	-1,000 - 9,889 feet (-305 - 3,014m)
Storage and transportation altitude	-1640 - 42,979 feet (-500 - 13,100m) Note: Requirements for the optional Nellcor® Oximax® SpO2 ((NELL-3): -1,000 - 20,000 feet (-305 - 6,096m)

1.2.4 Power Requirements

Voltage:	AC 100-240 V, 50/60 Hz
Power:	70VA

1.2.5 Rechargeable Battery

- Rechargeable lead-acid battery, 2.3 Ah, 12V
  Minimum of 260min:
  The monitor runs on power supplied by the new fully-charged battery in the following conditions:
  Ambient temperature: 25℃
  Monitor configuration: SpO_2 (Continuous measurement) and NIBP (one auto NIBP measurement per 15min)
  Charge time: Maximum of 8h
- Lithium battery, 4.4Ah, 11.1V
  Minimum of 620min
  The monitor runs on power supplied by the new fully-charged battery in the following conditions:
  Ambient temperature: 25℃
  Monitor configuration: SpO_2 (Continuous measurement) and NIBP (one auto NIBP measurement per 15min)
  Charge time: Maximum of 8h
- Time to shutdown at low battery power: 5 to 15min after the first battery-low alarm (a new fully-charged battery should be used)

Chapter2 Principles of Operation

2.1 General

The whole system consists of mechanical, hardware and software parts, as follows:

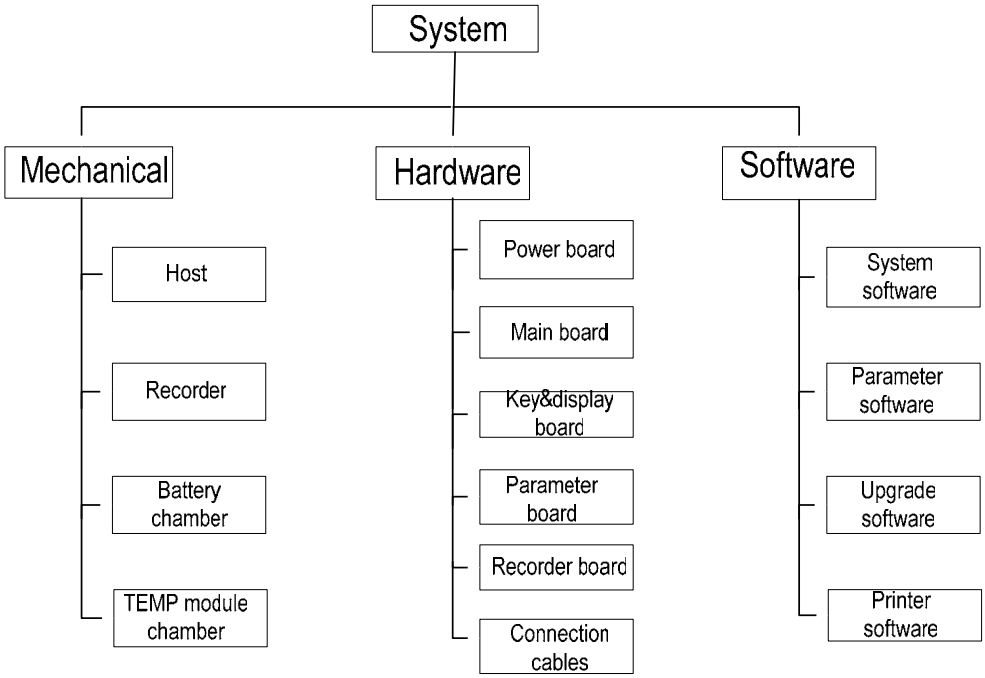

Figure 1 System structure

As shown in Figure 2-1, the VS-800 Vital Signs Monitor consists of

- 4 mechanical parts: host, recorder, TEMP module chamber and rechargeable battery chamber;
- 6 hardware parts: main board, key&displays board, parameter boards, recorder board, connection cables and power board;
- 4 software parts: System software, Parameter software, Upgrade software and printer software.

2.2 Hardware Description

The hardware structure of the VS-800 is shown as Figure 2-2:

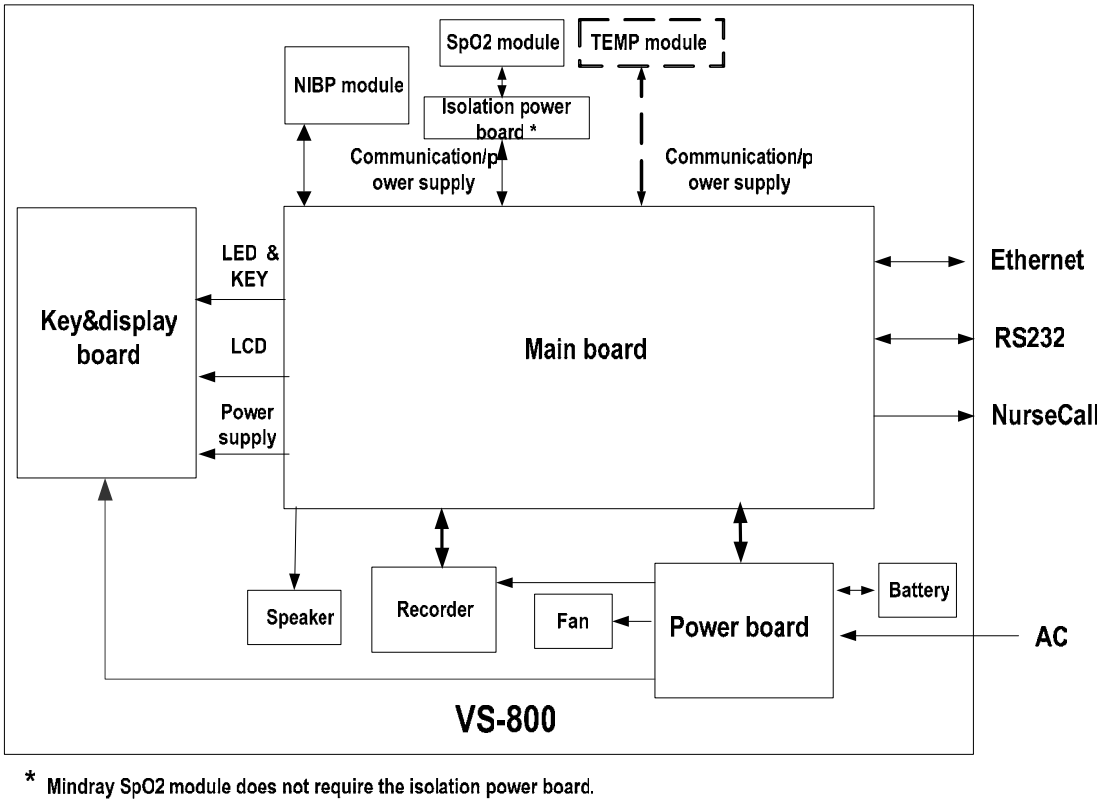

Figure 2 Structure of hardware

Note1: The TEMP module mentioned in this manual is reserved for future use.

The hardware connections of the VS-800 Vital Sings Monitor are as shown in Figure 2-3:

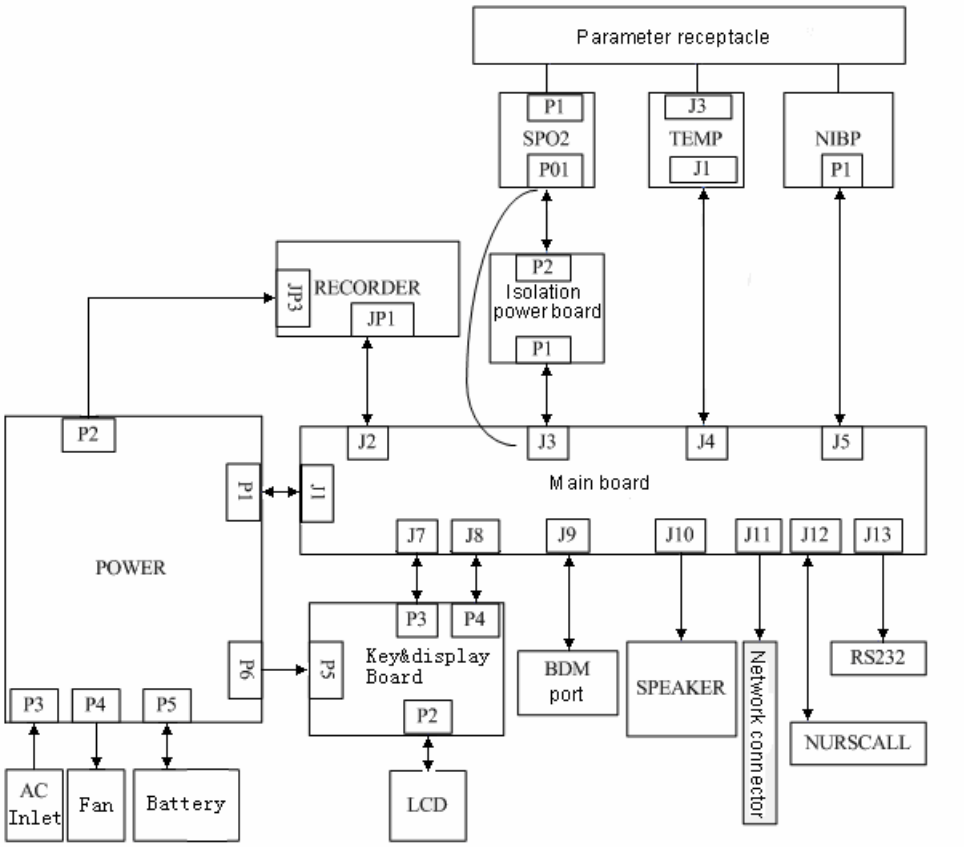

Figure 3 Connections of VS-800 hardware

As shown in the figure above, the core of the system is the main board, from which the power is adapted to all parameter modules; the parameter modules directly communicate with the main board, and the measurement and status of all modules are controlled by the main board. The functions and operation principles of the VS-800 hardware parts are detailed respectively in the following sections.

2.2.1 Main Board

2.2.1.1 Principle diagram

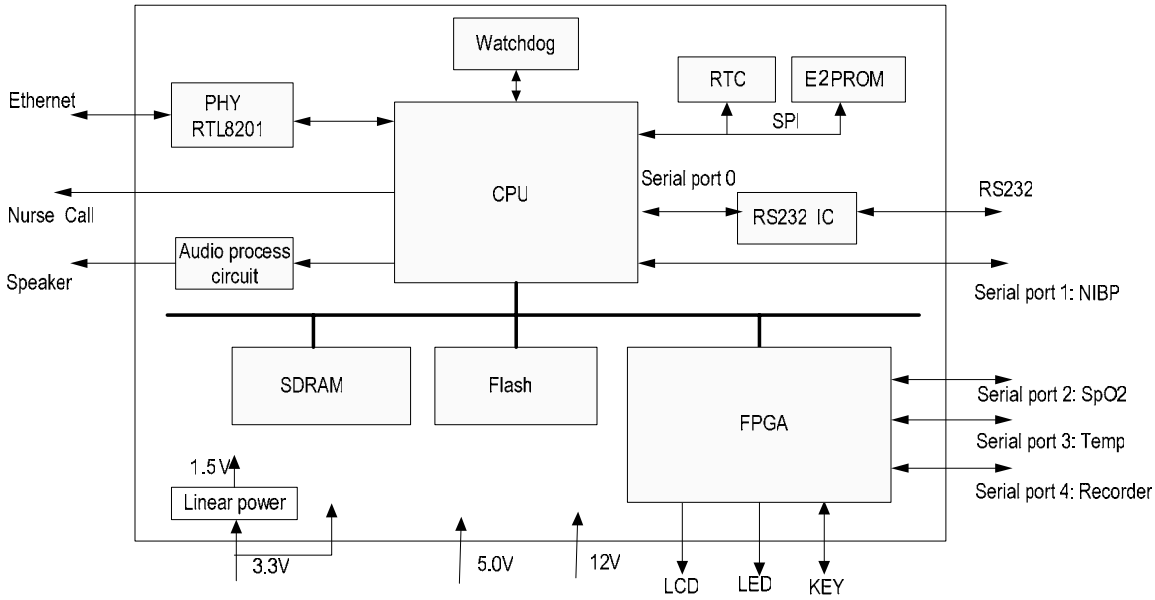

Figure 4 Operation principle of the main board

2.2.1.2 Principle

The main board communicates with all parameter modules and recorder module through serial ports; the power of the parameter modules is adapted from the main board.

The main board supplies displaying information for the key&displays board detects the keys and realizes the user's interface.

The audio process circuit of the main board drives the speaker, thus to realize audible alarms, key tones and PITCHTON.

The main board controls the alarm indicator through the signal wire is adapted from the key&displays board.

In addition, the main board provides the nurse call connector, network connector and R232 connector.

The real-time clock is realized by the RTC chip to which the power is supplied from AC mains or by the battery when available. When the AC power or battery is unavailable, the built-in battery of the RTC chip supplies the power, thus guaranteeing the normal working status of the clock.

SDRAM is responsible for storing data temporarily and running programs; FLASH serves as the system program memory and trend data memory; E^2PROM serves as the device configuration memory.

2.2.1.3 Units of main board

2.2.1.3.1 FPGA

FPGA is used for:

- Controlling STN-LCD

The PFGA drives the display of the monochromatic STN-LCD module, including the RAM and displaying sequence; it communicates with the key&displays board CPLD.

The FPGA transmits data displayed by LEDs and receives key information by Means of communicating with keypad CPLD through synchronous serial port.

- Extending serial ports

The FPGA extends 3 serial ports for the communications with parameter modules.

- Extending I/O port

The FPGA extends the I/O port for controlling the NURSE CALL circuit.

- Generating frequency-adjustable signal

The FPGA generates the frequency-adjustable signal which is used by the audio process circuit.

1. Audio process circuit

Following the common scheme regarding the key&displays board audio process circuit, the audio process circuit generates envelope signals by using the PWM function of the CPU, and generates audio frequency signals by using the FPGA.

2. ADC circuit

The ADC circuit detects ADV, +12V and battery voltages as well as the battery status voltage by using the A/D converter. The A/D converter Provides a I^2C bus interface. The CPU simulates the I^2C bus signal with two I/O ports.

3. Network connector

To guarantee that the earth wire of the network connector can pass the 1500V high-voltage test, isolated components such as the network transformer must be placed near the RJ45 socket and kept a specific distance from other components.

4. RS232 connector

The RS232 connector is made of the UART module of the CPU and the RS232 chip. The RS232 chip has the ESD protection function (±15KV).

5. NURSE CALL connector

The NURSE CALL connector controls the NURSE CALL signal by using an I/O port extended

by the FPGA.

2.2.2 Power Board

2.2.2.1 General

The power board converts the power input (from AC mains or battery) to different working voltages for other boards; it also has the function of charging the battery.

2.2.2.2 Principle diagram

According to the design requirements, the power board can be divided into three parts: AC/DC isolation converter, DC/DC converter and charging circuit, as shown in Figure 2-5.

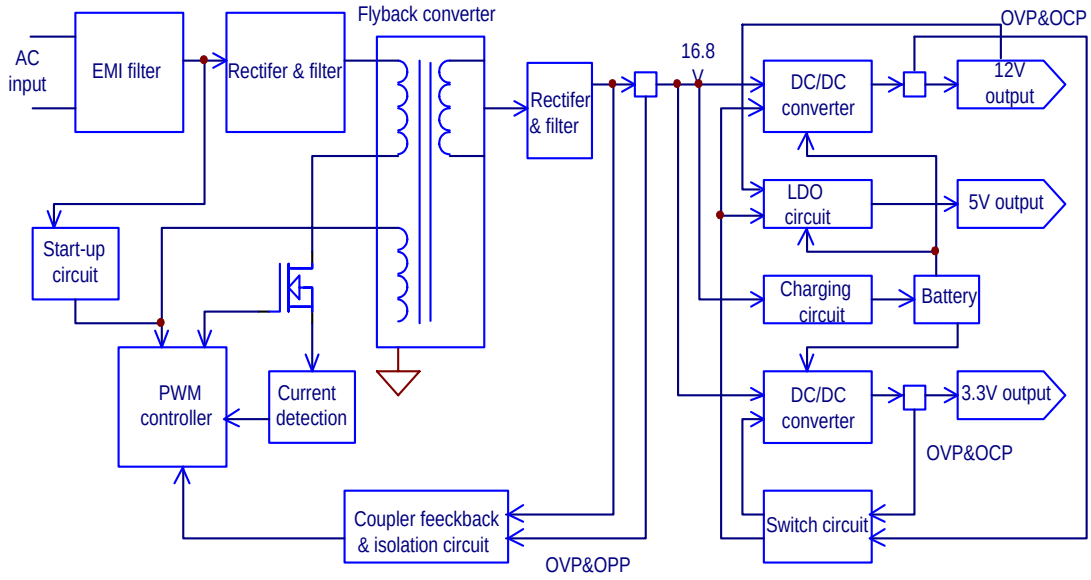

Figure 5 Operation principle of the power board

2.2.2.3 Principle

After the AC input reaches the power board through the connection board, it flows through the EMI filter circuit and rectifier and filter circuit. Then it is converted to a DC voltage, which is further converted to the 16.8V DC voltage by the Flyback converter. The 16.8V DC voltage is the main input of the DC/DC converter and charging circuit; it is used to charge the lithium battery or lead-acid battery, and also converted to 12V, 5V and 3.3V DC voltages by corresponding DC/DC converters and LDO circuit. In case the AC input is unavailable, the battery can supplies power for the DC/DC converters to get the 12V, 5V and 3.3V DC voltages. Meanwhile, the 12V, 5V and 3.3V DC outputs are under the control of the switch signal.

The 16.8V DC output is protected against over-voltage and over-power; the 12V and 3.3V DC

outputs are protected against over-voltage, short-circuit and over-current; the 5V DC output is protected against over-voltage and short-circuit.

2.2.3 Key&displays board

2.2.3.1 General

The key&displays board provides the user's interface. The main board supplies the power for the key&displays board. The LCD module, 7-segment digit display, LED indicators and keys are integrated on this board.

Principle diagram

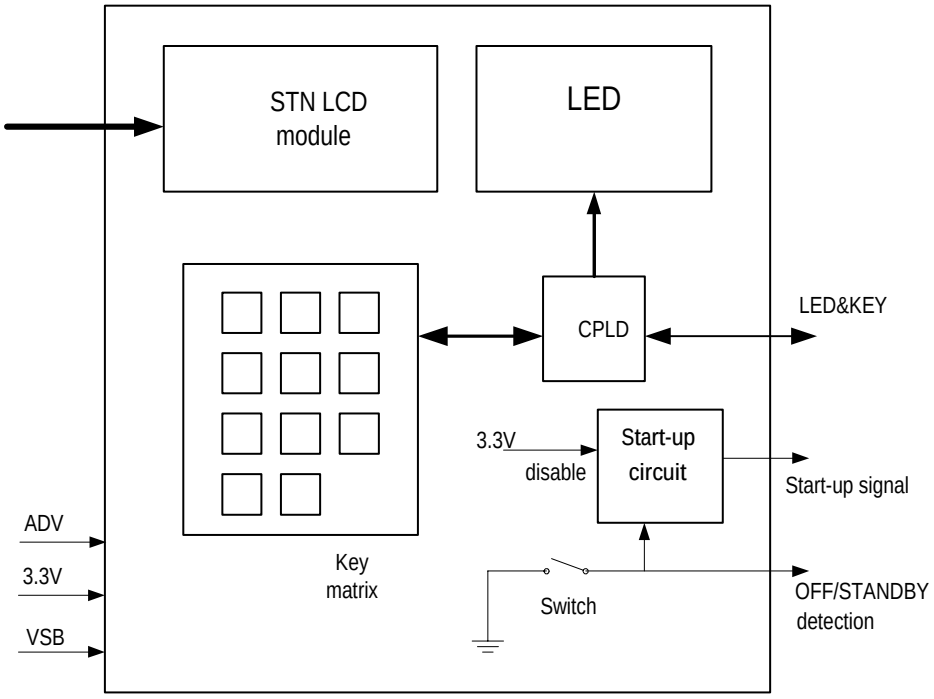

Figure 6 Operation principle of the key&displays board

2.2.3.2 Units

2.2.3.2.1 LCD module

This module has the function of adjusting the contrast and brightness in 10 levels,

Self-provided drive.

The FPGA controls the LCD. It transmits data signals and control signals to the LCD drive to realize the display on the LCD.

The main board supplies the 3.3V power for the logic part of the LCD module, and the power board supplies the 3.3V power for the backlight assembly.

This module displays menus, trend data and plethysmograms.

2. 2. 3. 2. 2 LED

There are Six groups of 7-segment digit display on the key&displays board. They are used for displaying the systolic pressure, diastolic pressure, mean pressure/cuff pressure, SpO_2 and PR; every group is of 3 digits.

The signal is transmitted from the main board FPGA to the CPLD, and is displayed by the 7-segment digit displays driven by the CPLD scanning.

The AC indicator is driven by the ADV voltage output from the power board.

The working status indicator (ON/STADNDBY indicator) is driven by the 3.3V voltage.

The battery indicator is controlled by the flash control signal, ADV signal and /BC signal together. When the system is powered by the battery only, the CPLD outputs the flash control signal and the battery indicator flashes; when the system is power by AC mains, the ADV voltage drives the battery indicator to ON. The /BC signal is transmitted from the power board to the cathode of the battery indicator. When there is no battery in the monitor, the resistance of the /BC becomes high, so the battery indicator will never become ON.

The bichrome LED alarm indicator is driven by the 3.3V voltage and controlled by the flash control signal output from the CPLD.

For other LED indicators, the anodes are connected to 3.3V voltages and are controlled by the CPLD I/O port.

The displaying and controling is signal of the indicators above is delivered from the main board FPGA to the CPLD.

2. 2. 3. 2. 3 Keys

There are totally 12 keys.

ON/STANDBY key: In the OFF status, press this key to power on the monitor; in the working status, press this key for less than 1s to enter the standby status. Press this key for more than 2s to power off the monitor.

The other 11 keys form a 3×4 matrix. The CPLD scans the key matrix, and performs the key debouncing after detecting any key input signal. If the input signal is valid, the CPLD saves the current key input code and transmits it to the main board.

2.2.4 SpO_2 Module

2.2.4.1 General

The SpO_2 module provides the function of measuring the Pulse Oxygen Saturation (SpO_2).

2.2.4.2 Principle diagram

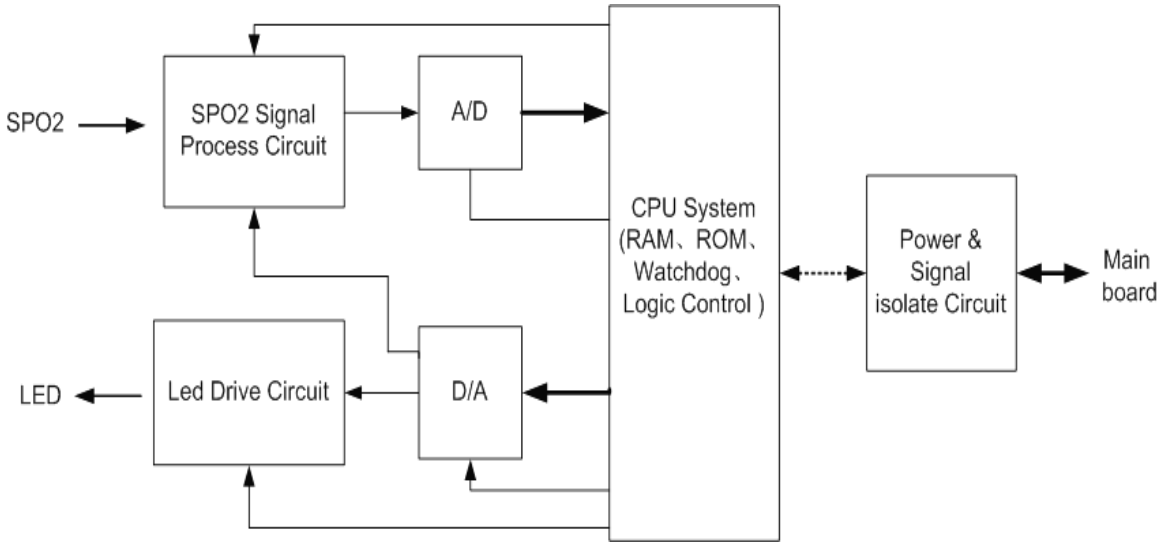

Figure 7 Operation principle of the SpO2 module

2.2.4.3 Principle

The SpO_2 measurement principle:

1. Collecting the light signal of the red light and infrared transmitting through the finger or toe which is pulsing;
2. Processing the collected signal to get the measured result.

The drive circuit of the LED and the gain of the amplifying circuit should be controlled according to the different perfusions and transmittances of the tested object.

2.2.4.3.1 Led Drive Circuit

This circuit supplies the LED with the drive current, which can be regulated.

2.2.4.3.2 SPO2 Signal Process Network

The pre-amplifying circuit converts the photoelectric signal to the voltage signal and conducts the primary amplification.

The gain adjusting and amplifying circuit conducts the secondary signal amplification and adjusts the gain.

The biasing circuit adjusts the dynamic range of the signal, and sends it to the A/D conversion part.

2.2.4.3.3 A/D

The A/D conversion part converts the analog signal to the digital signal, and then sends it to CPU for further processing.

2.2.4.3.4 D/A

The D/A conversion part converts the digital signal received from CPU to the analog signal, and provides the control signal for the Led Drive Circuit and SPO2 Signal Process Network.

2.2.4.3.5 CPU System

- Implementing the logical control of all the circuits;
- Implementing the data processing for the SpO_2 parameter;
- Implementing the communication with the main board.

2.2.4.3.6 Power & Signal isolate Circuit

- Isolating the external circuits to ensure the safety of human body;
- Supplying power for all circuits;
- Implementing the isolation communication between the CPU System and the main board.

2.2.5 NIBP Module

2.2.5.1 General

This module provides the function of measuring the Non-Invasive Blood Pressure (NIBP).

2.2.5.2 Principle diagram

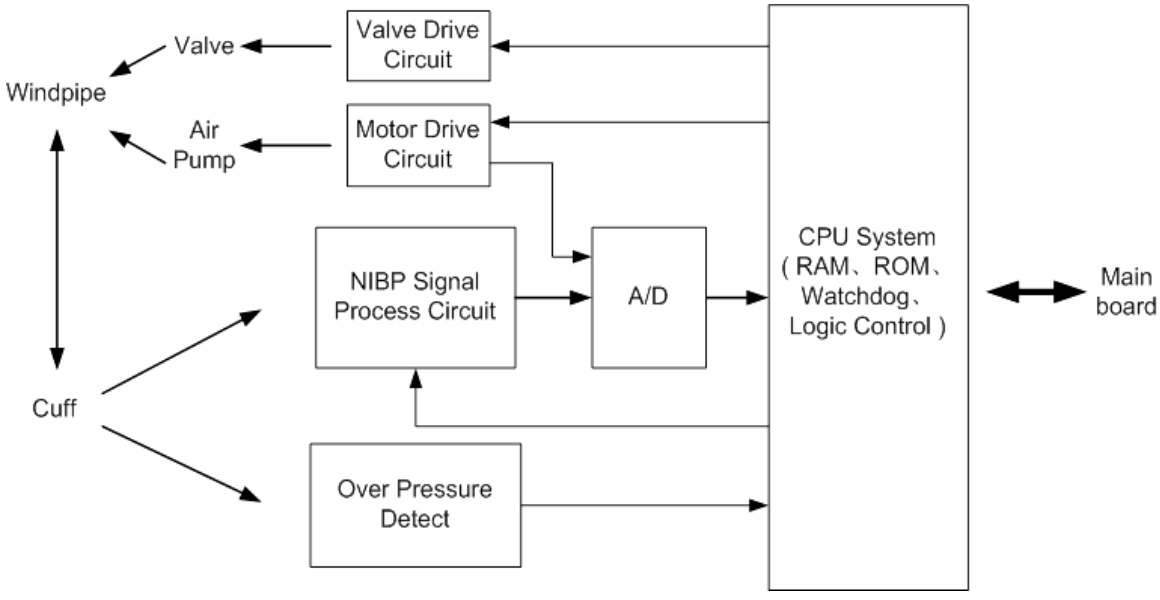

Figure 8 Operation principle of the NIBP module Principle

The NIBP is measured based on the pulse vibration principle. Inflate the cuff which is on the forearm till the cuff pressure blocks the arterial blood, and then deflate the cuff according to a specified algorithm. While the cuff pressure is decreasing, the arterial blood has pulses, which are sensed by the pressure transducer in the cuff. Consequently, the pressure transducer, connected with the windpipe of the cuff, generates a pulsation signal, which is then processed by the NIBP module to get the NIBP value.

2.2.5.2.1 Valve Drive Circuit

This circuit controls the status (ON/OFF) of valves. It, together with the Motor Drive Circuit, implements the inflation and deflation of the cuff.

2.2.5.2.2 Motor Drive Circuit

This circuit controls the action of the air pump. It, together with the Valve Drive Circuit, implements the inflation and deflation of the cuff. Besides, it provides the status signal of the motor for the A/D conversion part.

2.2.5.2.3 NIBP Signal Process Network

The NIBP signal is the differential input signal. The difference amplifying circuit amplifies the dual-end difference signal and converts it to the single-end signal; meanwhile, this circuit sends a channel of signal to the A/D conversion part, and the other to the DC isolating and amplifying circuit.

The DC isolating and amplifying circuit removes DC components from the signal, amplifies the signal, and then sends it to the A/D conversion part.

2.2.5.2.4 A/D

The A/D conversion part converts the analog signal to the digital signal, and sends it to the CPU System for further processing.

2.2.5.2.5 Over Pressure Detect

The circuit detects the NIBP pressure signal. Once the pressure value exceeds the protected pressure value, it will send a message to the CPU System, which asks the Valve Drive Circuit to open the valve to deflate the cuff.

2.2.5.2.6 CPU System

- Implementing the logical control of all the circuits;
- Implementing the data processing for the NIBP parameter;

- Implementing the communication with the main board.

2.3 Software Description

2.3.1 General

2.3.1.1 Composition of software

The VS-800 software consists of the system software, module software, upgrade software and printer software.

Besides the system software, all the other software components are universal. Therefore, the following sections will emphasize on the requirements of the system software. For other software, only references are provided.

表 2-1 VS-800 software components

Software component		**Description**	**Material code of universal component**
System software		For different configurations (SpO_2 only and full configuration), the LED requires two different kinds of software.	(Non-universal)
Bootstrap software		Bootstrap upgrade software	0010-30-12196
Module software	NIBP	SIC33209 write software of 630D blood pressure pump	630D-30-09112
	MINDRAY SpO_2	S1C33209 write software of the SpO_2 board	9006-30-33911
	MASIMO SpO_2	MASIMO M7 SpO_2 software	(See Note 1)
	Nellcor SpO_2	NELLCOR MP506 SpO_2 software	
	Recorder	33209 write software of the MCU	TR6C-30-16656

Note 1: Those software components are external, namely, they are not developed by Mindray.

2.3.2 System Software

2.3.2.1 General

The functions of the system software are shown in Figure 2-9:

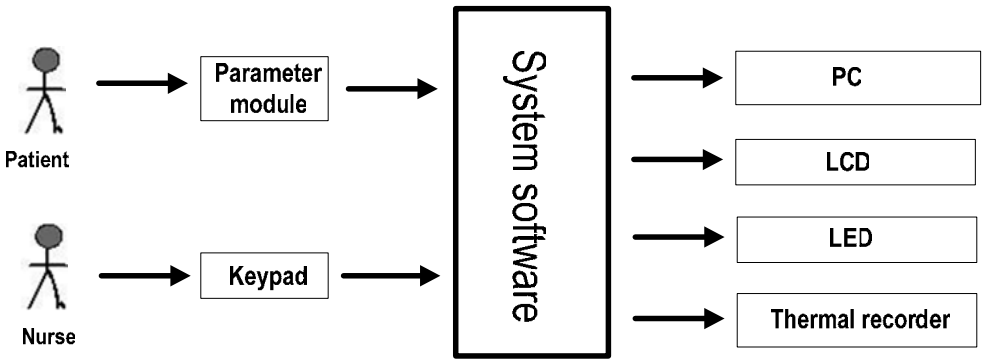

Figure 9 Function of system software

The VS-800 software provides the following functions:

1 Transmitting/receiving data to/from modules;

2 Displaying parameters, plethysmograms and trend data;

3 Rising alarms;

4 Controlling the recorder;

5 Reviewing patient history data;

6 Network function;

7 NURSECALL function;

8 Power management;

9 Displaying measurement results with LEDs;

10 Outputting data to PC for permanent storage and data printing.

2.3.2.2 Functions of system software

2.3.2.2.1 Power management

A. The system detects the battery and battery volume automatically, and power LED gives status of battery.

B. The system detects the voltage (12V) of the main board periodically. Once the voltage exceeds 12V limit, stop the ongoing NIBP measurement.

2.3.2.2.2 Parameter measurement

The parameter measurements are performed respectively by parameter modules. The system software is responsible for processing data and displaying the results.

2.3.2.2.3 Data output

Trend data can be recorded. The recorded data can be queried on the LCD, output by the

recorder or through the network. In addition, the monitor can be connected to the central monitoring system, thus performing data output.

2.3.2.2.4 Alarm paused/silenced

The audible alarms are compliant with IEC60601-1-8.

The alarm pause period is 2 minutes; the system can also be silenced.

2.3.2.2.5 Network

Central Monitoring System (CMS)

Data output

Software upgrade

2.3.2.2.6 Pitch Tone

With the Pitch Tone function, the system can dynamically change the pulse tone.

Nurse Call

The Nurse Call function is used for outputting alarms.

2.3.2.2.7 Standby

When the monitor receives no physiological signals or gives a battery-low alarm,

In the monitoring status, press the ON/STANDBY key for less than 2s. The CONFIRM STANDBY STATE dialog box appears, prompting “Enter the Standby State. Yes?” Select YES to enter the standby status.

In the standby status, press any key on the front panel of the monitor. The EXIT STANDBY dialog box appears, prompting “Enter monitoring state?” Select YES to exit the Standby status and enter the monitoring status. If no operation is done within 30 seconds, the monitor will automatically select NO, this dialog box will disappear, and the monitor will keep in the Standby status.

The monitor exits the standby status and enters the monitoring status automatically when

- The monitor receives SpO_2 physiological signal for 5 seconds or more;
- The monitor is powered by the internal battery which is to be depleted.

2.3.2.2.8 Mode modification

A. Format of date: Chinese (-year-month-day); European: (day-month-year); American (month -day- year). The review date of the trend data corresponds to the system time.

B. Precision of real-time clock: ±1 minute/month at 213±℃.

Display resolution: 1s

Range: 2001 0: 0: 0 -2099 23: 59: 59

2.3.2.2.9 Alarm message

A. Alarms include physiological alarms and technical alarms，Alarms classed 3 grade：high、middle and low alarm.

a) Every parameter has an alarm switch. If the alarm function of a parameter is disabled, no audible and visual alarm will be given in case exceptions occur.

b) The alarm function is compliant with relevant standards.

B. Alarm mode

a) The speaker and alarm indicator give the audible and visual alarms, the LED flashes, and alarm messages are displayed on the LCD.

b) When alarms of the two alarm levels occur, the system gives the high-level alarm.

C. If the monitor is connected to the Nurse Call system properly, the alarm, if any, can be given through the Nurse Call system. The reviewed trend data begin to be stored.

2.3.2.2.10 Non-volatile data storage

The monitor can store modified configurations. Besides the factory default configuration, the monitor can store 1 group of user default configuration for each patient type.

Storage of trend data: In the full configuration, the non-volatile data include trend data of all parameters: systolic pressure, mean pressure, diastolic pressure, PR, SpO_2, measurement time and patient ID.

2.3.3 Module Software

The module software implements the upper-level communication protocol through the communication port.

2.3.4 Upgrade Software

The upgrade software implements, through the Ethernet and PC, the online upgrade of the system software of the monitor and module software.

The upgrade software package includes the bootstrap and PC upgrade software. The bootstrap, which takes the main board as the platform, provides the online upgrade functions of system software and module software as well as the system function configuration. The PC

upgrade software, which takes the PC as the platform, communicates with the monitor through the Ethernet, and provides operators with the upgrade/configuration UI.

The FPGA upgrade software is controlled by the main board.

The upgrade software realizes the multi-language downloading and upgrade function.

2.3.5 Printer Software

The printer software, which takes the PC as the platform, receives data output from the monitor, and implements the data display, storage and printing.

2.4 System Parameters

2.4.1 NIBP

The NIBP is measured based on the pulse vibration principle. Inflate the cuff which is on the forearm till the cuff pressure blocks the arterial blood, and then deflate the cuff according to a specified algorithm. While the cuff pressure is decreasing, the arterial blood has pulses, which are sensed by the pressure transducer in the cuff. Consequently, the pressure transducer, connected with the windpipe of the cuff, generates a pulsation signal. Then, the pulsation signal is filtered by a high-pass filter (about 1Hz), amplified, converted to the digital signal by the A/D converter, and finally processed by the MCU. After that, the systolic pressure, diastolic pressure and mean pressure can be obtained. For neonates, pediatric and adults, it is necessary to select the cuffs of a proper size to avoid possible measurement errors. In the NIBP measurement, there is a protection circuit used to protect patient from over-high pressure.

The NIBP measurement modes include:

1) Adult/pediatric/neonate mode: To be selected according to the build, weight and age of the patient;

2) Manual/Auto/Continuous mode: The manual measurement is also called single measurement; in this mode, only one measurement is done after being started. In the auto measurement mode, the auto measurement be done according to the preset procedure. In the continuous measurement mode, quick continuous measurement will be done within 5 minutes after being started; it detects the changes in blood pressure effectively.

2.4.2 SpO_2

The SpO_2 value is obtained through the pulse waves of the finger tips based on specific

algorithm and clinical data. The SpO_2 probe is the measurement transducer. It has two inbuilt LEDs and an inbuilt light receiver. The two LEDs include one red-light diode and one infrared diode, which emit light in turns. When the capillaries in the finger tip are iteratively congested with blood pumped by the heart, the light emitted by the LEDs, after absorbed by the capillaries and tissue, casts on the light receiver, which can sense, in the form of electric signal, the light strength changing with the pulsated blood. The DC/AC ratio of the two photoelectric signals corresponds to the content of the oxygen in the blood. Therefore, the correct pulse oxygen saturation can be obtained with specific algorithm. Moreover, the pulse rate can be obtained according to the pulse waveform.

The circuit of the SpO_2 module is involved in four parts: SpO_2 probe, signal processing unit, LED-driven sequencing control part and the MCU.

For your notes

Chanpter3 Product Specifications

3.1 Type of Monitor

Type of protection against electrical shock	Class I, internally powered equipment
EMC	Class A
Degree of protection against electrical shock	NIBP/SpO_2: CF, Defibrillation-proof Monitor: B
Degree of protection against harmful ingress of water	Not suitable (ordinary)
Degree of protection against hazards of ignition of flammable anesthetic mixtures	Not suitable (ordinary)
Methods of sterilization	Refer to the operation manual for detailed information
Mode of operation	Continuous operation

3.2 Specifications of Monitor

3.2.1 Dimension and Weight

Dimension	170 x 240 x 170 mm
Weight	< 3.5kg (Full configuration, battery included)

3.2.2 Operating Environment

3.2.2.1 Temperature Requirements

Operating ambient temperature	0℃ - 40℃
Storage temperature	-20℃ - 60℃

3.2.2.2 Relative Humidity

Operating relative humidity	15% - 95% (non-condensing)
Transportation and storage relative humidity	10% - 95% (non-condensing)

3.2.2.3 Power Requirements

Voltage:	AC 100 - 240 V, 50/60 Hz (± 3 Hz)
Power:	70VA
Switch :	Standby

3.2.3 Specifications of Display

- LCD display

Dot matrix:	320×160
Dot pitch:	0.24×0.24
Dot size:	0.225×0.225
LCD type:	FSTN LCD
Polarity:	Positive
Transmission mode:	Transflective
Viewing angle:	12:00
Type of backlight:	LED (4 white LEDs)

- Displayed contents:

  Startup screen

  Trend data (including scroll bar)

  SpO_2 waveform (can be switched)

  Menu (pop up)

  Time

  Prompting messages

- 5 groups of LED digit displays:

  Used to display the systolic pressure, diastolic pressure, mean pressure/cuff pressure, SpO_2 and PR.

- 6 groups of monochrome LED indicators

  Used to display or indicate the pulse strength, power, ADULT-PEDIATRIC-NEO (patient type), mmHg-Kpa (unit of pressure), silence function and NIBP measurement status.

3.2.4 Signal Interface

Nurse call output	The nurse call function is designed for the nurse call system in hospital
Type of nurse call signal	Relay signal, always ON/OFF (optional)
Maximum voltage	12V DC (no greater than 13V DC)
Maximum load current	≤2A
Connection resistance	<1Ω
Isolation voltage	>1500V AC
Network interface	For connection to the Central Monitoring Network, software upgrade and data export

3.2.5 Battery

No. of batteries:	1
Battery type:	Sealed lead-acid battery or lithium ion battery
Time to shutdown at low battery power:	5-15min after the first low-battery alarm (a new fully-charged battery should be used)

3.2.5.1 2.3 Ah 12V Sealed Lead-Acid Battery

- Minimum of 260min

The monitor runs on power supplied by the new fully-charged battery in the following conditions:

Ambient temperature: 25℃

Monitor configuration: SpO_2 (Continuous measurement) and NIBP (one auto NIBP measurement per 15min)

- Charge time: Maximum of 8h. Operating status.

3.2.5.2 4.4Ah 11.1V Lithium Ion Battery

- Minimum of 620min

The monitor runs on power supplied by the new fully-charged battery in the following conditions:

Ambient temperature: 25℃

Monitor configuration: SpO_2 (Continuous measurement) and NIBP (one auto NIBP measurement per 15min)

- Charge time: Maximum of 8h. Operating status.

3.2.6 Recorder

Method	Thermal dot array
Horizontal resolution	160dots/cm (25 mm/s)
Vertical resolution	80dots/cm
No. of waveform channels	1
Paper width	50±0.1 mm
Paper length	30m
Paper speed	25 mm/s, ±5%
Record mode	The recorder should support 3 record modes: 1) Recording current trend data being displayed on the LCD of the current patient 2) Recording all patient trend data Recording waveform graphs continuously in real time

3.2.7 Review

Trend review

Storage of trend data: Displayed contents of full configuration:

Data in trend tables of all working parameters, including systolic pressure, mean pressure, diastolic pressure, pulse rate, SpO_2, measurement time and patient ID.

Display resolution: SpO_2 configuration only: Once per minute (mean measured value within 1min.)

Other configurations: Minimum interval is 1min.

Maximum storage: 1200 groups of data

Storage of data

Storage of monitor configurations: The monitor should be capable of storing changeable configurations. Besides the factory default configuration, one group of user default configuration for each patient type should be stored.

The following data should be stored:

1. Patient information
2. Alarm limit settings
3. Volume settings
4. Recorder settings
5. Clock settings
6. Parameter settings

Storage of patient information: The current patient information is stored in the non-volatile memory.

3.2.8 NIBP

Measuring method	Automatic oscillometry
Mode of operation	Manual/Automatic/Continuous
Measuring interval for automatic mode:	1,2,3,4,5,10,15,30,60,90,120,180,240,480min
Measuring time for continuous mode:	5min
Maximum measurement cycle	

Adult/pediatric:	180s
Neonate:	90s

PR:

Range	40 - 240 bpm
Accuracy	±2 bpm or ±2%, whichever is the greater
Resolution	1bpm

- Measurement range in normal mode

Adult:

Systolic pressure:	40 - 270mmHg
Diastolic pressure:	10 - 210mmHg
Mean pressure:	20 - 230mmHg

Pediatric:

Systolic pressure:	40 - 200mmHg
Diastolic pressure:	10 - 150mmHg
Mean pressure:	20 - 165mmHg

Neonate：

Systolic pressure:	40 - 135mmHg
Diastolic pressure:	10 - 100mmHg
Mean pressure:	20 - 110mmHg

Resolution:

Pressure:	1mmHg

Accuracy:

Pressure	
Max. mean error	±5mmHg
Max. standard error	8mmHg

- Software over-pressure protection: The over-pressure detection is controlled by software. Once the cuff pressure exceeds the threshold, the software enables the system to deflate the cuff.

Adult	300 mmHg
Pediatric	243mmHg
Neonate	150 mmHg

- Hardware over-pressure protection: In single fault conditions, the hardware controls the cuff deflation to prevent the cuff pressure from exceeding the following ranges.

Adult	330 mmHg
Pediatric	330mmHg
Neonate	165 mmHg

3.2.9 SpO_2

3.2.9.1 MASIMO SpO_2

- Range

SpO2 (%)	1% - 100%
PR (bmp)	25 - 240

- Accuracy

SpO_2 (%)	No motion conditions
Adult/pediatric	70% - 100%: ±2%
	0% - 69%: Undefined
Neonate	70% -100%: ±3%
	0% - 69%: Undefined
SpO_2 (%)	During motion conditions
Adult/pediatric/neonate	70% -100%: ±3%
	0% - 69%: Undefined
PR (bpm)	No motion conditions
	25 - 240 ± 3 BPM
PR (bpm)	During motion conditions
	25 - 240 ± 5 BPM

- Resolution

SpO_2 (%)	1%
PR (bpm)	1

- Response time

Under the condition that the PR is 75BPM and the mean time is 8s, the maximum response time for the SpO_2 value to increase from 60% to 95% is 20s.

3.2.9.2 9006 Sp02

Range:	0 - 100%
Resolution:	1%

- Accuracy

No motion conditions:

Patient Type	SpO_2 range	
	70% to 100%	0 - 69%
Adult (including pediatric)	± 2 digits	Undefined
Neonate	± 3 digits	Undefined

- Updating cycle of SpO_2 values: 1s
- PR

Range: 20 - 254 BPM

Resolution: 1bpm

- Accuracy

Patient Type	PR range	Accuracy(No motion conditions)
Adult/Pediatric/Neonate	20-254 bpm	± 3 digits

3.2.9.3 Nellcor SpO_2

Range and accuracy for SpO_2 measurement:

Sensor	Accuracy [1]
MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST	70% - 100% ± 2 % 0% - 69% Undefined
OxiCliq A, OxiCliq N, OxiCliq P and OxiCliq I	70% - 100% ±2.5 % 0% - 69% Undefined
D-YS, DS-100A, OXI-A/N and OXI-P/I	70% - 100% ± 3 % 0% - 69% Undefined
MAX-R, D-YSE and D-YSPD	70% - 100% ± 3.5 % 0% - 69% Undefined

Range and accuracy for PR measurement:

Range	Accuracy
20 - 250 BPM	±3 BPM
251 - 300 BPM	Undefined

Updating cycle of SpO_2 values: 1s

For your notes

Chanpter4 Machine Disassembly/Assembly and Troubleshooting

4.1 Disassembly/Assembly Figure

4.1.1 Host Assembly

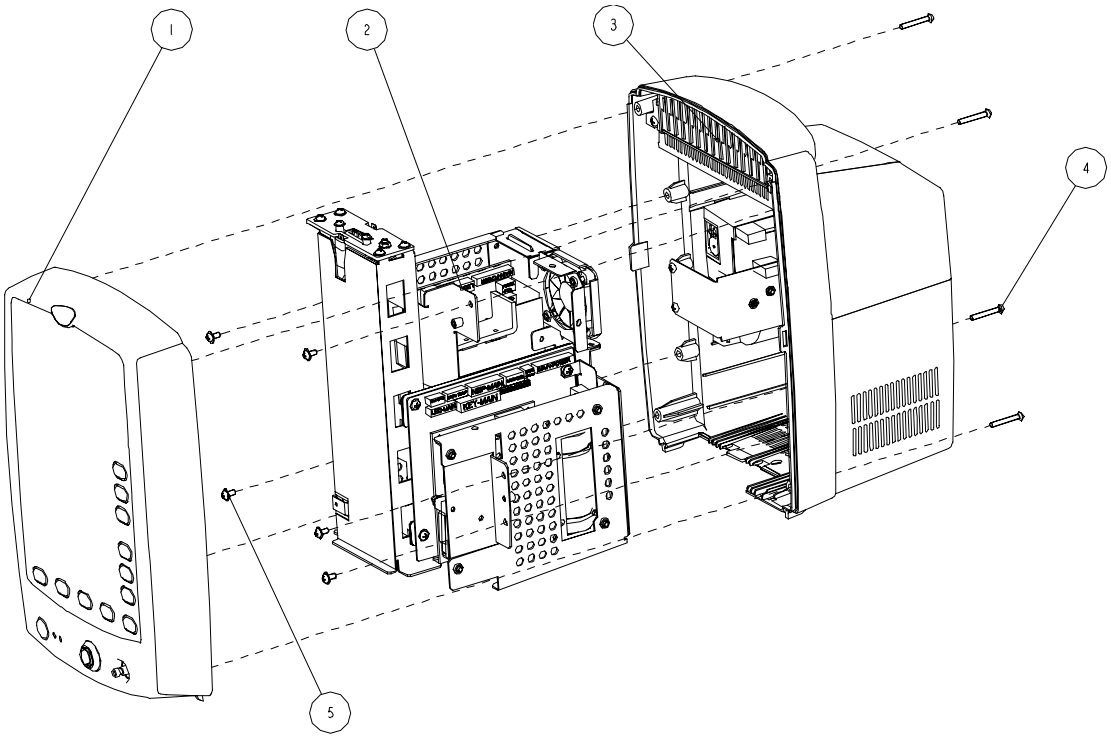

Figure 1 Host assembly

No.	Std. Code	Name & Spec.	Qty.
1	6006-30-39446	Front housing component	1
2	6006-30-39401	Master bracket component (lead-acid)	1
3	6006-30-39447	Rear housing component	1
4	M04-000505---	Cross pan head screwM3X20	4
5	M04-004012---	Cross pan head screw with washer M3X6	5

4.1.2 Master bracket (lead-acid battery) assembly

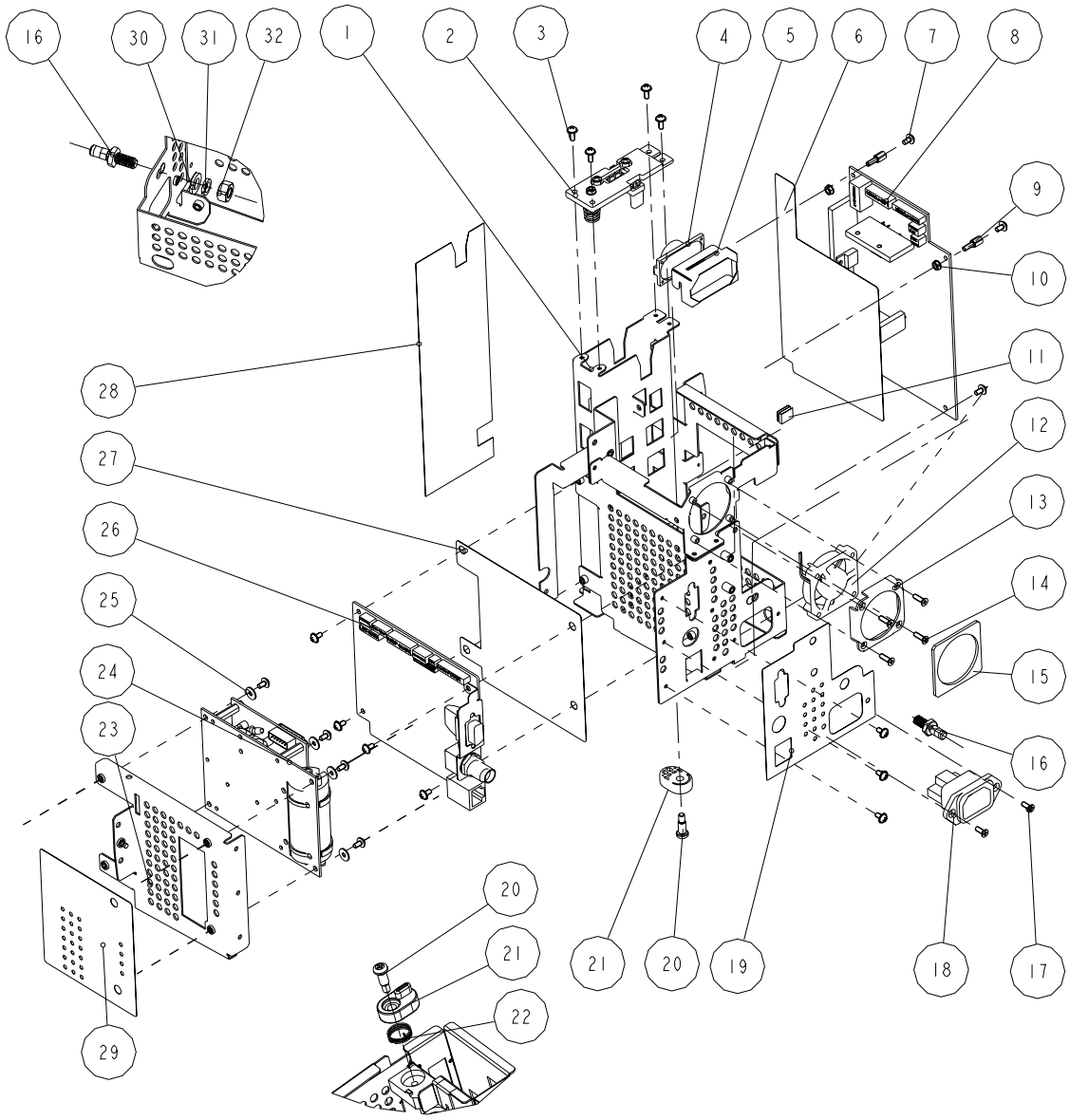

Figure 2 Master bracket (lead-acid battery) assembly

No.	Std. Code	Name & Spec.	Qty.
1	6006-20-39367	Main bracket (lead-acid battery)	1
2	6006-30-39448	Lead-acid battery assembly	1
3	M04-004015---	Gasketed cross-head screw M3*8	4
4	6006-20-39385	Speaker & connection cables	1
5	6006-20-39379	Washer of speaker	1
6	6006-20-39464	Insulating plate of power board	1

7	M04-004012---	Gasketed cross-head screw M3*6	16
8	6006-20-39478	Lead-acid battery power board	1
9	M04-000106---	Screw M3X7+8-6	2
10	M04-011002---	M3 nut with external-tooth spring washer	2
11	0000-10-10996	EMI finger-like beryllium-copper spring plate92-047	2
12	6006-20-39387	Fan & connection cables	1
13	6006-20-39373	Fan support	1
14	M04-002005---	Cross-head sunk screw M3*12	4
15	6006-20-39434	Fan washer	1
16	0509-20-00098	Grounding connector	1
17	M04-000405---	Cross-head sunk screw M3*8	2
18	6006-21-39386	Power outlet	1
19	6006-20-39421	Overlay of external interface	1
20	6006-20-39486	Retaining screw for button battery	1
21	7000-20-24365	Battery baffle	1
22	6006-20-39485	Torsional spring for button battery	1
23	6006-20-39368	NIBP bracket	1
24	630D-30-09121	630D blood pressure pump	1
25	M04-021024---	Large flat washer GB96 3	4
26	6006-20-39352	Main board	1
27	6006-20-39451	Insulating plate for main board	1
28	6006-20-39450	Insulating plate for keypad	1
29	6006-20-39509	Overlay of NIBP bracket	1
30	M04-021003---	Flat washer GB97. 1 6	1
31	M04-004504---	Spring washer GB93 6	1
32	M04-004401---	Stainless steel nut GB6170 M6	1

4.1.3 Master bracket (lithium) assembly

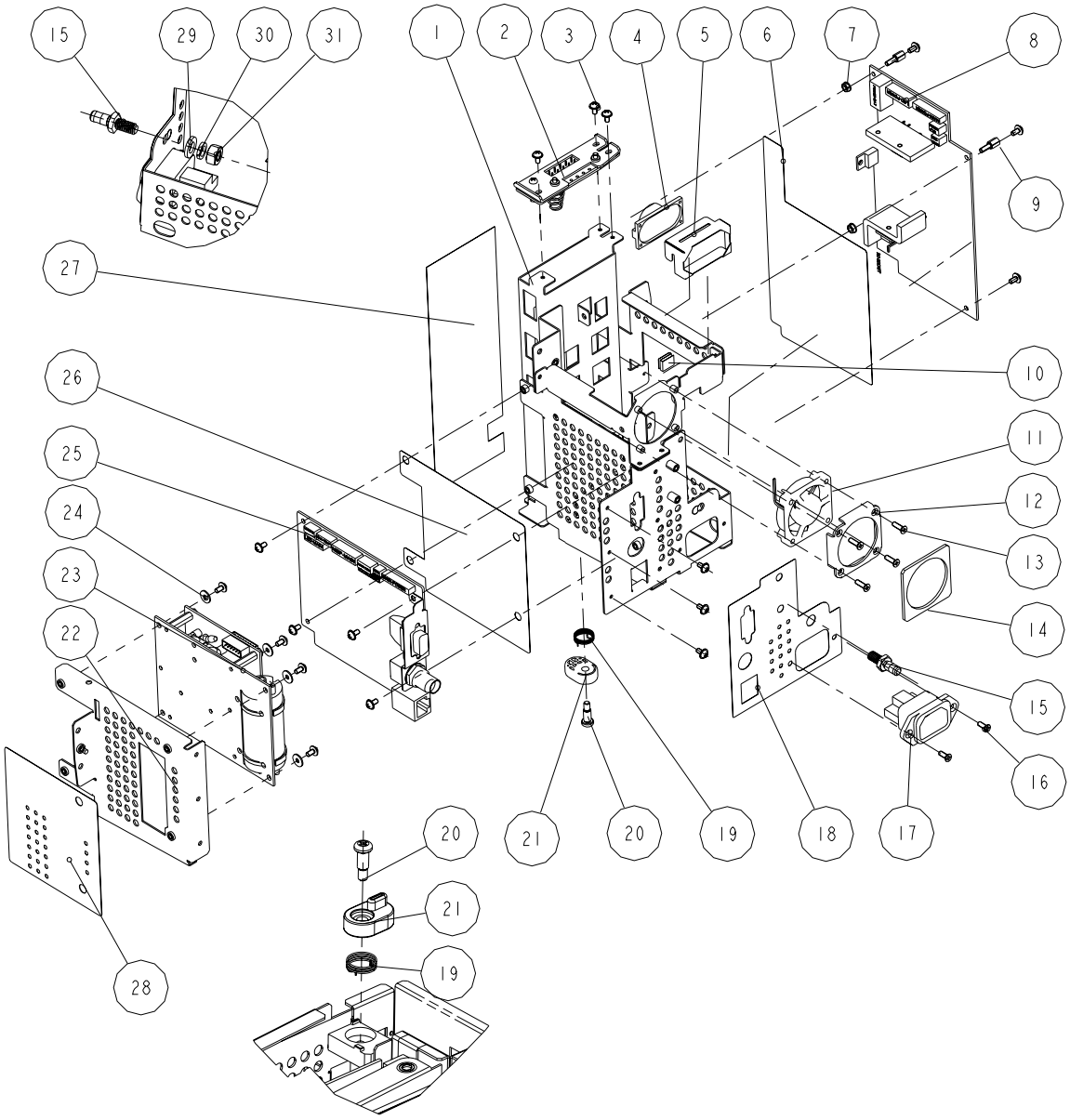

Figure 3 Master bracket (lithium) assembly

No.	Std. Code	Name & Spec.	Qty.
1	6006-20-39416	Master bracket (lithium)	1
2	6006-30-39449	Lithium battery component	1
3	M04-004012	Gasketed cross-head screw M3*6	17
4	6006-20-39385	Speaker and connection line	1
5	6006-30-39379	Speaker press plate	1

6	6006-30-39464	Insulating plate for power board	1
7	M04-011002---	M3 nut, with spring washer	1
8	6006-20-39393	Lithium power board	1
9	M04-000106---	Screw M3X7+8-6	2
10	0000-10-10996	EMI finger-shape beryllium-copper spring plate92-047	2
11	6006-20-39387	Fan and connection line	1
12	6006-20-39373	Fan rack	1
13	M04-002005---	Cross flat countersunk screwM3X12	4
14	6006-20-39434	Fan washer	1
15	0509-20-00098	Grounding connector	1
16	M04-000405---	Cross flat countersunk screwM3X8	2
17	6006-20-39386	Power inlet	1
18	6006-20-39421	Overlay of external interface	1
19	6006-20-39485	Torsional spring for button battery	1
20	6006-20-39486	Fastening screw for button battery	1
21	7000-20-24365	Battery baffle	1
22	6006-20-39368	NIBP bracket	1
23	630D-30-09121	630D blood pressure pump	1
24	M04-021024---	Large flat washer GB 96 3	4
25	6006-20-39352	Master control board	1
26	6006-20-39451	Insulating plate for master control board	1
27	6006-20-39512	Insulating plate(lithium) for keypad	1
28	6006-20-39509	Overlay of NIBP bracket	1
29	M04-021003---	Flat washer GB97. 1 6	1
30	M04-004504---	Spring washer GB93 6	1
31	M04-004401---	Stainless steel nut GB6170 M6	1

4.1.4 Front shell assembly

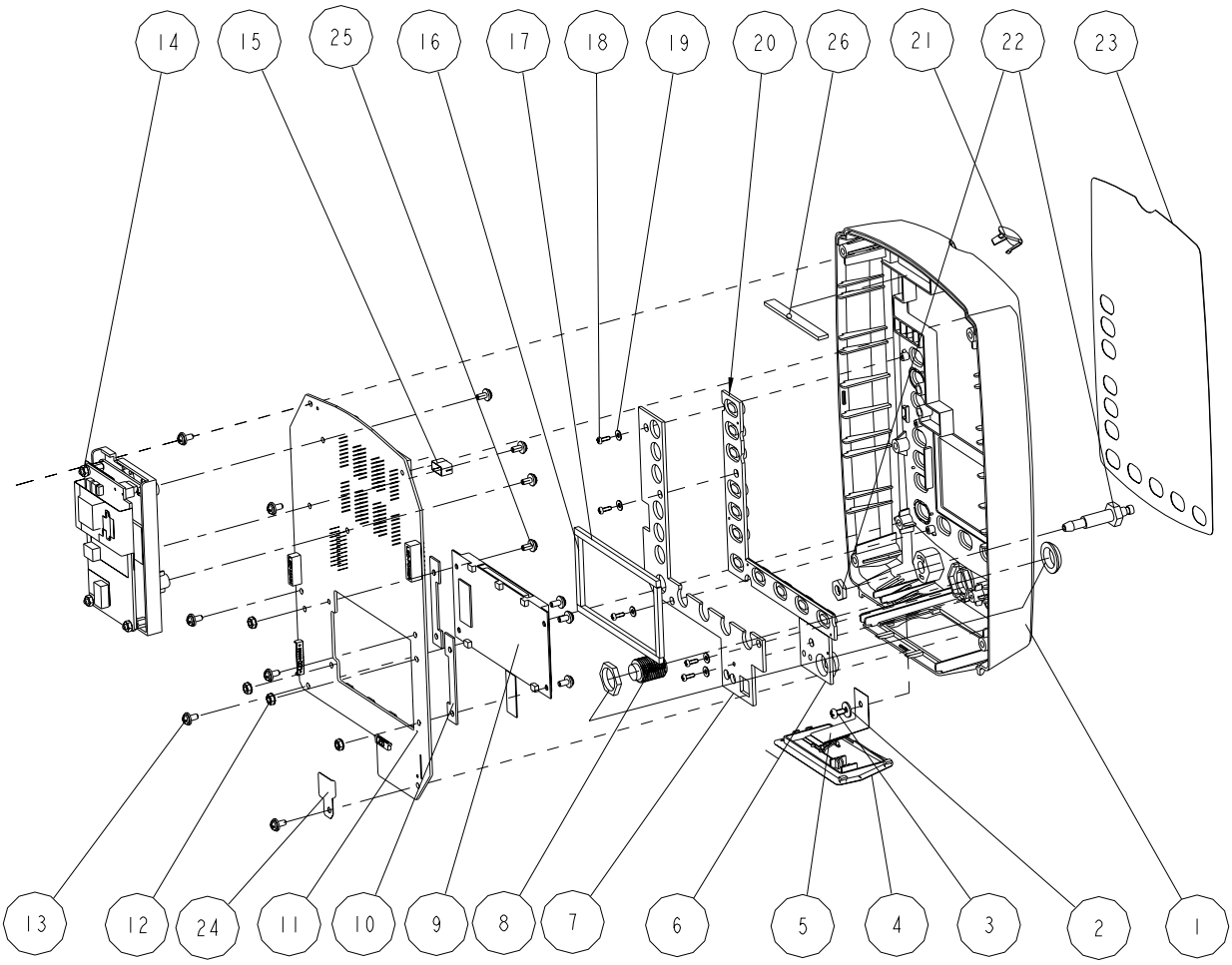

Figure 4 Front shell assembly

No.	Std. Code	Name & Spec.	Qty.
1	6006-20-39358	front cover	1
2	M04-021024---	Large flat washer GB 96 3	1
3	M04-003905---	cross pan head screw, pointless, self-tapping	1
4	6006-20-39359	battery door	1
5	6006-20-39376	battery door tape	1
6	6006-20-39415	silcon power button	1
7	6006-20-39431	silicon keypad press plate	1
8	6006-21-39391	masimo spo2 signal line	1
9	0000-10-10997	LCD	1

10	6006-20-39502	LCD backplate	2
11	6006-20-39354	keypad	1
12	M04-011002--	M3 nut with spring washer	4
13	M04-004012---	cross pan head screw, with washer M3X6	9
14	6006-20-39471	spo2 module	1
15	6006-20-39482	LED shade	4
16	6006-20-39488	dust panel1	2
17	6006-20-39487	dust panel2	2
18	M04-051003---	cross pan head screw, pointless, tail-cut, self-tapping	5
19	M04-021000---	flat washer	5
20	6006-20-39372	silicon button	1
21	6006-20-39361	alarm light cover	1
22	0010-20-12194	pneumatic connector assembly	1
23	6006-20-39420	front overlay	1
24	6006-20-39508	earthing washer	1
25	M04-004015---	cross pan head screw, with washer M3X8	4
26	6006-20-39520	Waterproof bar	1

4.1.5 Back shell assembly

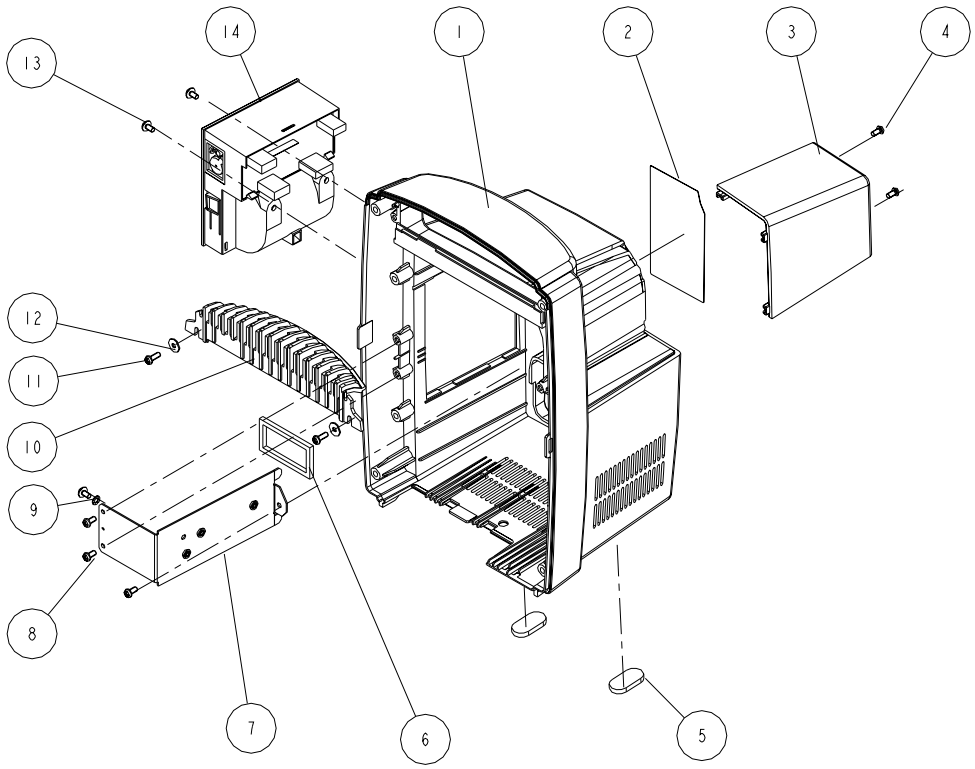

Figure 5Back shell assembly

No.	Std. Code	Name & Spec.	Qty.
1	6006-20-39351	Back shell	1
2	6006-20-39374	Label (Chinese)	1
3	6006-20-39362	Temperature module cap (No temperature)	1
4	M04-002505---	Cross head screw M3x6	2
5	6006-20-39375	Foot cushion	2
6	6006-20-39418	Speaker cushion	1
7	6006-20-39369	Support for recorder	1
8	M04-003905---	Tapping screw PT3X6	3
9	M04-000603---	External teeth washer GB862.1 3	1
10	6006-20-39350	Handle cap	2
11	M04-003105---	Cross head tapping screw PT3X8	2
12	M04-021024---	Washer GB96 3	2
13	M04-004012---	Cross head washer screw M3X6	3

14	TR6C-30-16654	TR60-C Recorder	1

4.1.6 Lithium battery assembly

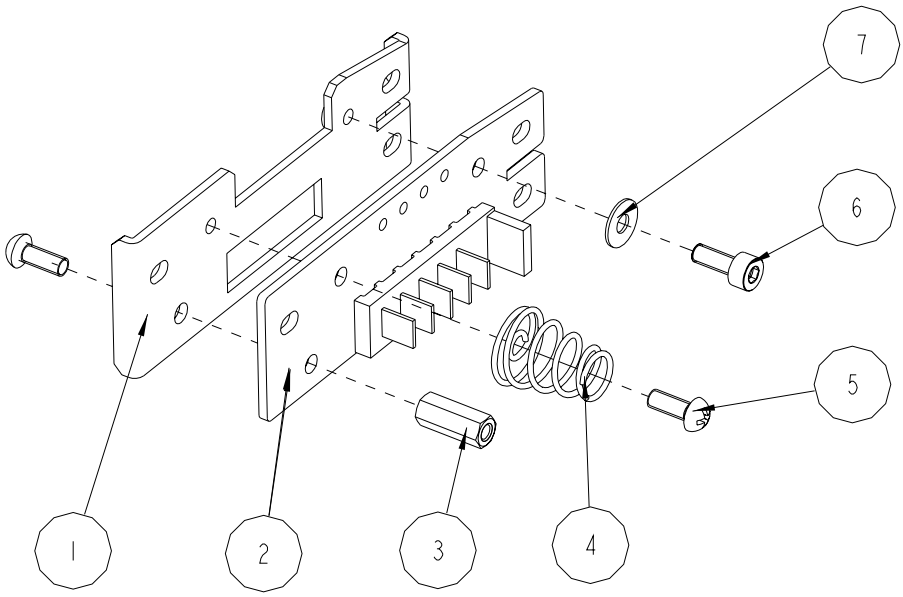

Figure 6Lithium battery assembly

No.	Std. Code	Name & Spec.	Qty.
1	6006-20-39417	Support for lithium battery	1
2	6006-30-39427	Lithium battery socket board	1
3	M04-030030---	Hexagon stud M3X12	1
4	9201-20-36038	Battery thrust spring	1
5	M04-000605---	Cross head screw M3X8	2
6	M04-051026---	Stainless socket head hexagon screw M3X10	1
7	M90-000002-03	Insulated washer Φ3X0.5	1

4.1.7 Lead-acid battery assembly

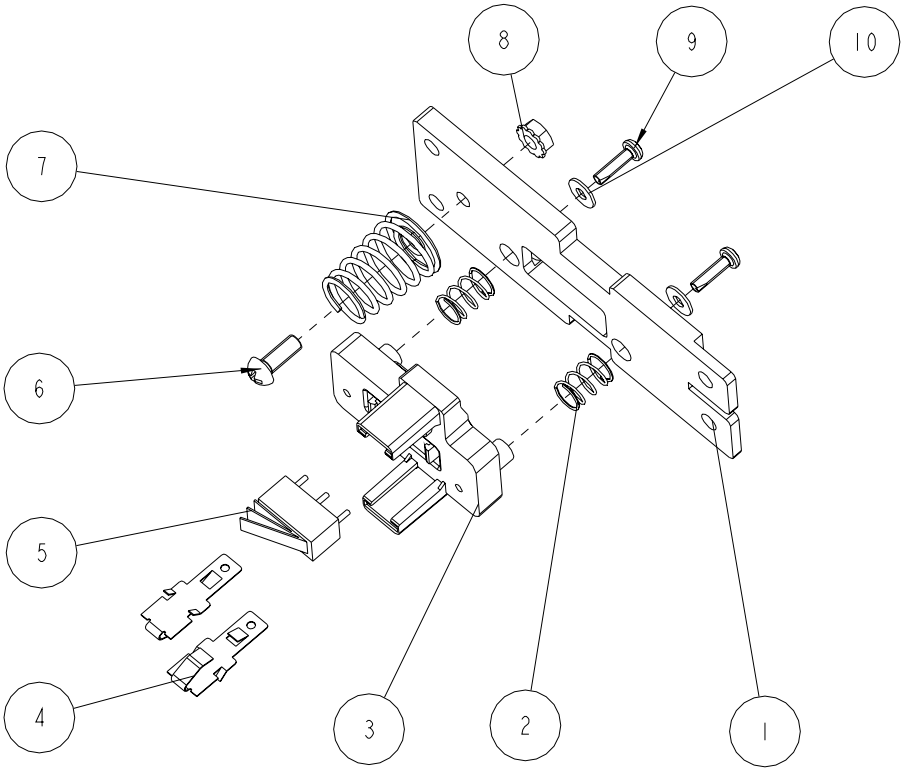

Figure 7Lead-acid battery assembly

No.	Std. Code	Name & Spec.	Qty.
1	6006-20-39419	battery fixed bracket	1
2	8002-20-36151	Adjustable spring	2
3	8002-20-36152	battery flexible bracket	1
4	8002-20-36154	battery contact	2
5	M07-00043S---	switch	1
6	M04-000605---	cross pan head screw M3X8	1
7	9000-20-07286	spring	1
8	M04-011002---	M3 nut, with spring washer	1
9	M04-051060---	cross pan head screw, pointless, tail-cut, self-tapping M2X8	2
10	M04-021000---	Washer GB 97.2 2.5	2

4.1.8 MASIMO SpO_2 board assembly

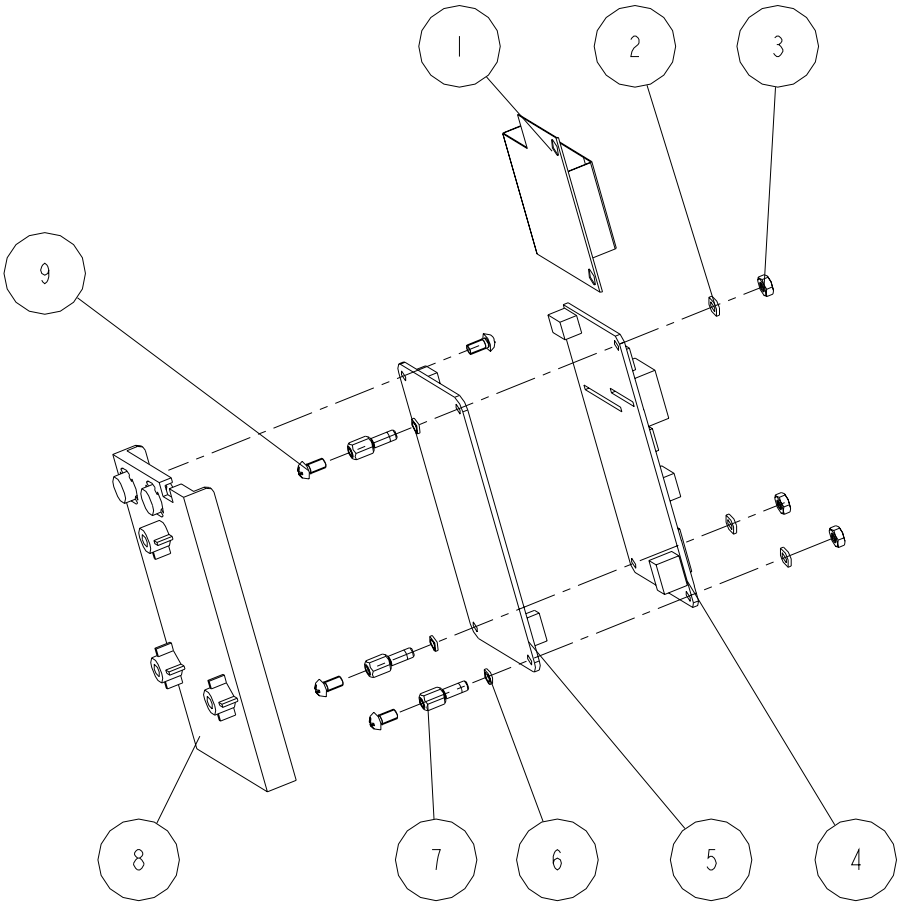

Figure 8MASIMO SpO_2 board assembly

No.	Std. Code	Name & Spec.	Qty.
1	DA8K-20-14524	Insulating plate of SpO_2 isolation power board	1
2	M90-000002---	Insulated washer Φ3X1	3
3	M04-000301---	NUT GB6170-M3	3
4	0010-30-12095	MASIMO M7 Isolation power board	1
5	0010-10-12275	MASIMO M7 BOARD（MASIMO KIT）	1
6	M04-000104---	Spring washer GB93 3	3
7	M04-000106---	Screw M3X7+8-6	3
8	6006-20-39366	SpO_2 mount bracket	1
9	M04-002505---	Cross-head screw M3*6	4

4.2 Inter-board Connections

4.2.1 List of Connection Cables

4.2.1.1 Signal lines

Name	Material number	Graphic connection relations
MINDRAY 9006 SPO2 signal line	6006-21-39390	See the figure below.
NELLCORE SPO2 signal line	6006-21-39392	See the figure below.
MASIMO SPO2 signal line	6006-21-39391	See the figure below.

4.2.1.2 Internal Connection Cables

Name	Material number	Graphic connection relations
Main board power cord	6006-20-39380	See the figure below.
Recorder signal line	6006-20-39381	See the figure below.
SpO2 module connection cables	6006-20-39382	See the figure below.
Keypad signal line	6006-20-39383	See the figure below.
LCD signal line	6006-20-39384	See the figure below.
Speaker and connection cables	6006-21-39385	See the figure below.
Power board AC input cables	6006-21-39386	See the figure below.
Fan and connection cables	6006-21-39387	See the figure below.
Power board-to-battery backplate connection cables (lithium)	6006-20-39388	See the figure below.
Power board-to-battery backplate connection cables (lead-acid)	6006-20-39389	See the figure below.
Recorder power cord	6006-20-39492	See the figure below.
Keypad power connection cables	6006-20-39493	See the figure below.
NIBP module connection cables	6006-20-39494	See the figure below.

4.2.1.3 Connection Cable Figure

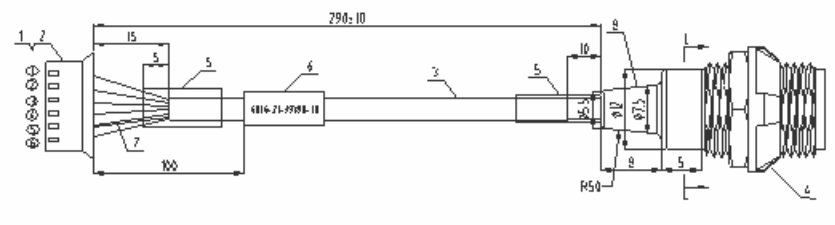

Figure 9MINDRAY 9006 SPO2 Signal Line

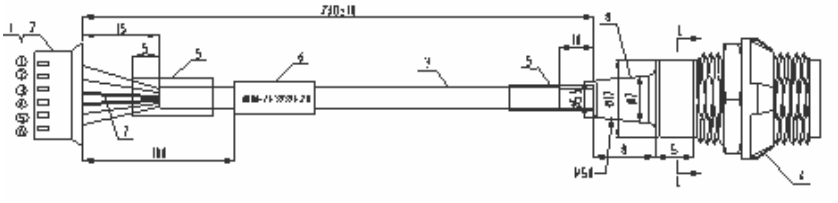

Figure 10MASIMO SPO2 Signal Line

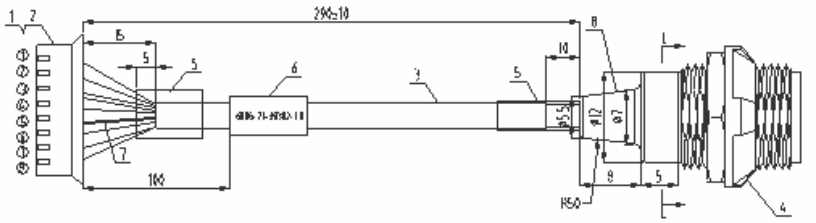

Figure 11NELLCORE SPO2 Signal Line

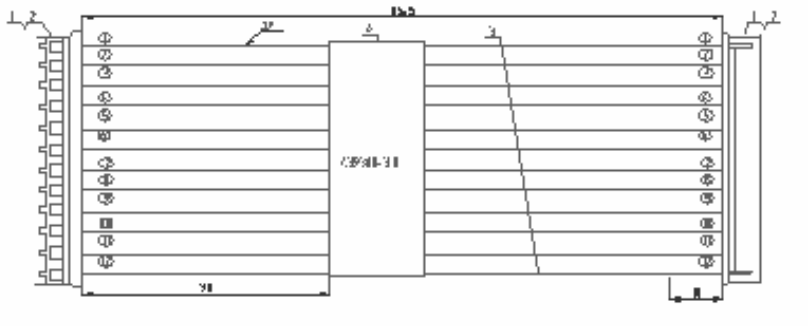

Figure 12Main Board Power Cord

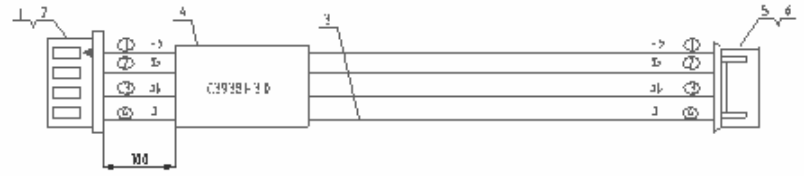

Figure 13Recorder Signal Line

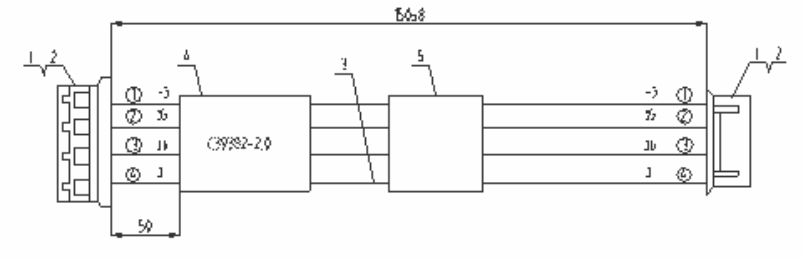

Figure 14SpO2 Module Connection Cables

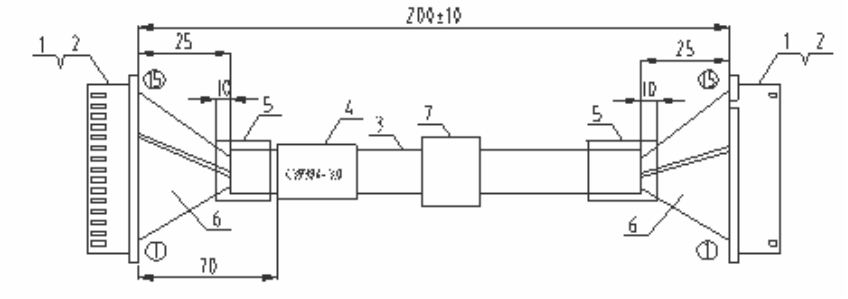

Figure 15LCD Signal Line

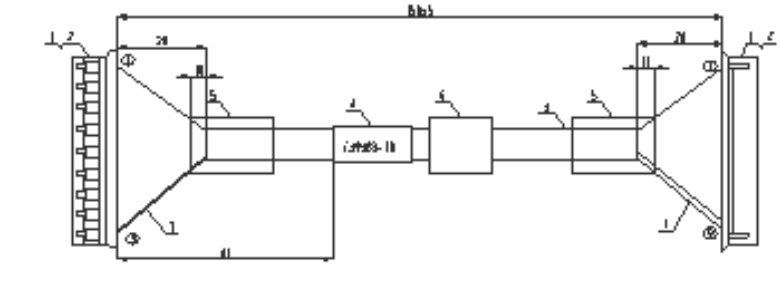

Figure 16Keypad Signal Line

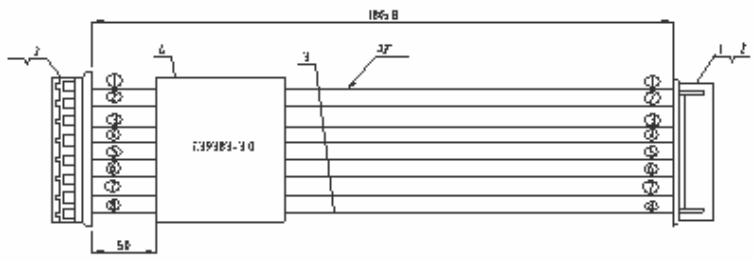

Figure 17Keypad Power Connection Cables

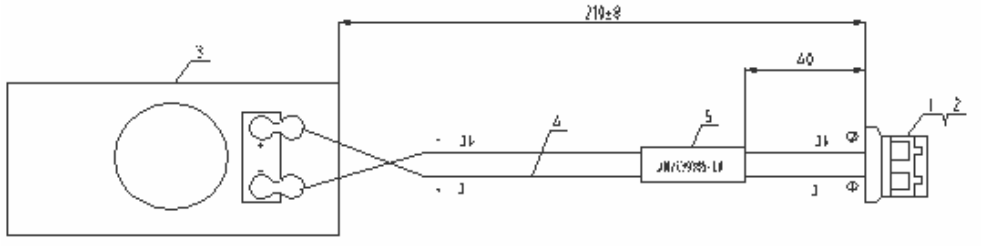

Figure 18Speaker and Connection Cables

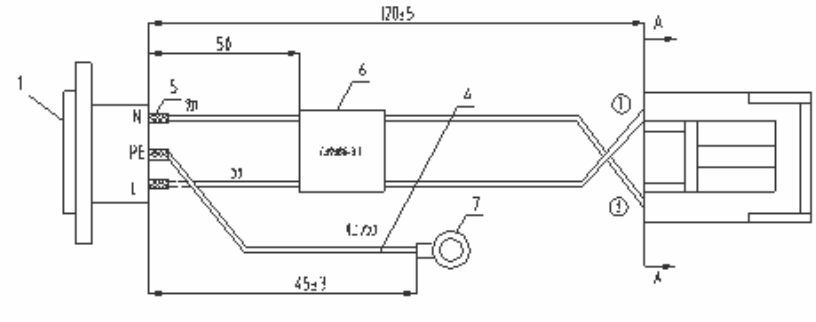

Figure 19Power Board AC Input Connection Cables

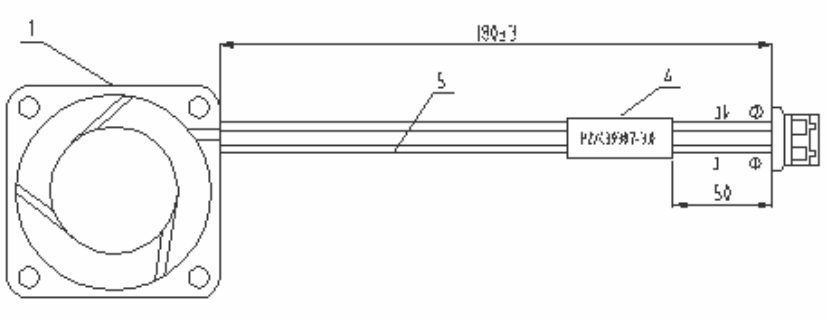

Figure 20Fan and Connection Cables

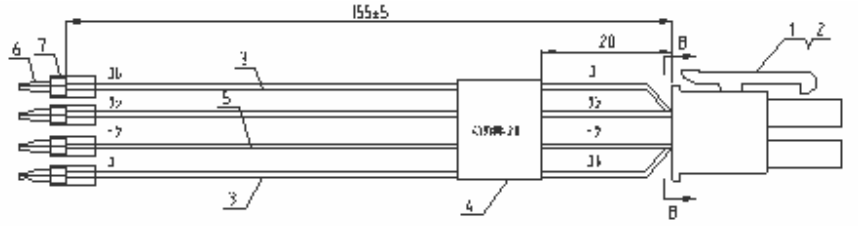

Figure 21Power Board-to-Battery Backplate Connection Cables (Lithium)

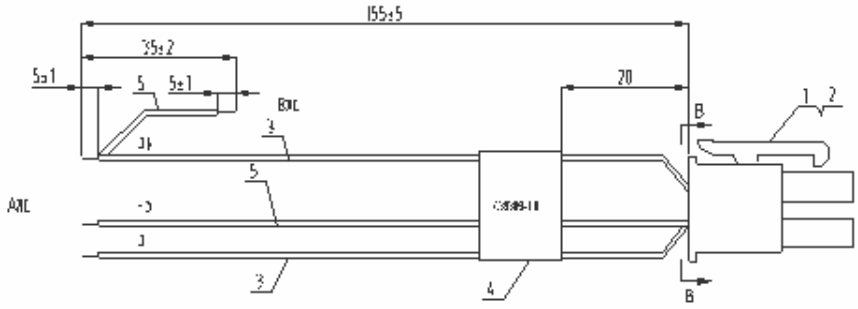

Figure 22Power Board-to-Battery Backplate Connection Cables (Lead-acid)

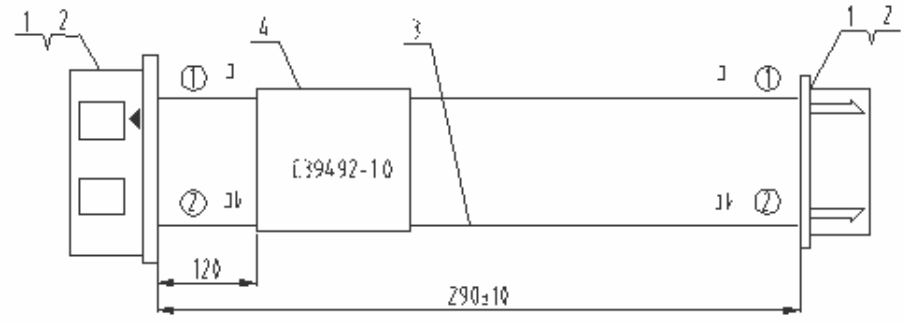

Figure 23Recorder Power Cord

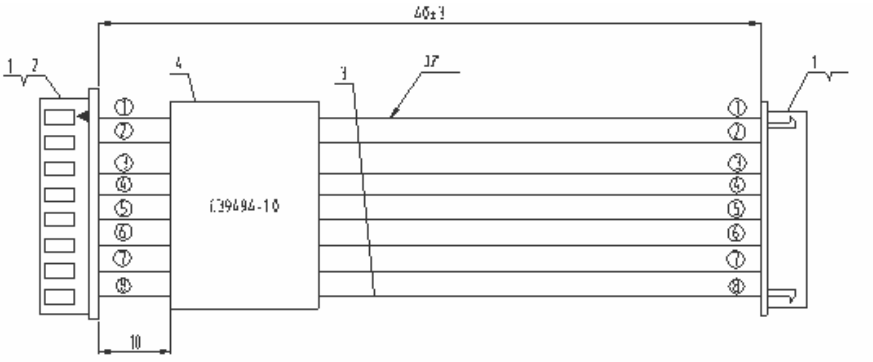

Figure 24NIBP Module Connection Cables

4.3 Troubleshooting

4.3.1 Cannot start

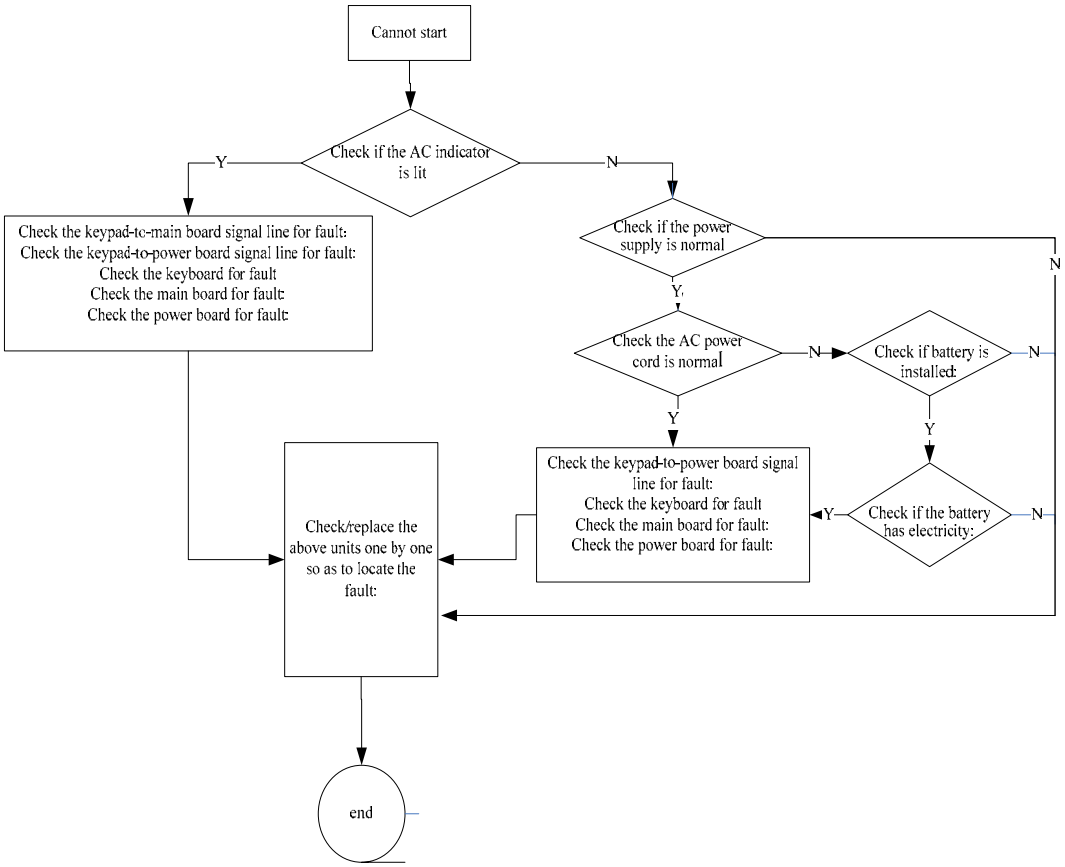
Cannot start
Check if the AC indicator is lit
Y
N
Check the keypad-to-main board signal line for fault:
Check the keypad-to-power board signal line for fault:
Check the keyboard for fault
Check the main board for fault:
Check the power board for fault:
Check if the power supply is normal
N
Y
Check the AC power cord is normal
N
Check if battery is installed:
N
Y
Y
Check the keypad-to-power board signal line for fault:
Check the keyboard for fault
Check the main board for fault:
Check the power board for fault:
Y
Check if the battery has electricity:
N
Check/replace the above units one by one so as to locate the fault:
end

Figure 25 Black Screen Troubleshooting Map

4.3.2 LCD Black, Backlight Off

1. Check if the LCD signal line is in good condition;
2. Check if the keypad power cord is in good condition;
3. If the problem still remains after the connection cables are replaced, replace the LCD module:
4. If the problem still exists, check the keypad, power board or main board.

4.3.3 LED Displays Abnormally

1. Check if the LED signal line is in good condition;
2. Check if the keypad power cord is in good condition;
3. Check if the button signal line is in good condition;
4. If the problem still exists, check the keypad, power board or main board.

4.3.4 Alarms Soundless

1. Check if the sound is turned off in the software setup;

2. Check the speaker connection cables;
3. Replace the speaker;
4. Replace the main board.

4.3.5 Cannot Print

1. Check if the software has recorder-related alarms. If yes, eliminate them;
2. Check if the recorder indicator is lit;
3. If not, check the recorder signal input connection cables;
4. Check the recorder power input connection cables (including the recorder power board);
5. Replace the recorder module.

4.3.6 Paper Travels Abnormally

1. Check if the recorder paper roller has got something;
2. Check if the recorder print head has got something;
3. Check if the recorder power voltage >7.8V.

4.3.7 NIBP cannot Work Correctly

1. Check if the NIBP hose is not obstructed;
2. Check if the NIBP signal line is in good condition;
3. Otherwise, replace the NIBP module.

4.3.8 SPO2 Works Abnormally

1. Check if the accessories are correct;
2. Check if the SpO2 signal line is in good condition;
3. Check if the SpO2 communication cable is in good condition;
4. Otherwise, replace the SpO2 module.

Chanpter5 Machine test and Material List

5.1 Test Procedure

Connect the simulators, power and fixture to the VS-800 and power it on. The LED and LCD modules should display correctly

5.1.1 Button Function Test

Press each button on the keypad. The VS-800 should give corresponding response and perform corresponding function. Refer to the VS-800's Operation Manual.

5.1.2 NIBP Test

After connecting the NIBP simulator, adult cuff and accessories properly, connect the cuff to the CUFF connector on the monitor and tighten it by turning clockwise.

1. After self-tests pass, press ENT to enter the ADULT mode. Set the simulator to the blood pressure 255/195/215 mmHg, SHIFT +15 and HR 80BPM, and the VS-800 to the ADULT mode. Press START for around 30 seconds, and the results will be calculated. The test results are 270±8mmHg, 210±8mmHg and 230±8mmHg.
2. Press ECS and↓ on the simulator to enter the NEONATE mode. Set the simulator to the blood pressure 120/80/90 mmHg and HR 120 BPM, and the VS-800 to the NEONATE mode. Press START for around 30 seconds, and the results will be calculated. The test results will be 120±8mmHg, 80±8mmHg and 90±8mmHg respectively.
3. Press ESC and ↓ on the simulator to enter the NEONATE mode. Set the simulator to the blood pressure 60/30/40 mmHg, SHIFT—20 and HR 120 BPM, and the VS-800 to the NEONATE mode. Change the simulator accessory to a neonatal cuff. Press START for around 30 seconds, and the result displayed should be 40±8mmHg, 10±8mmHg and 20±8mmHg.

5.1.3 SpO2 Test

Insert a finger into the SpO2 sensor. The screen should display the values of PR and SpO2 correctly. The normal SpO2 should be above 97%.

5.1.4 Recorder Print Test

1. Print SpO2 graph. The recorder should print correctly and the printed results should be clear and consistent. If set such faults such out of paper, etc., corresponding prompts should be given. After the fault is removed, the VS-800 should be able to work correctly.
2. Print trend data. The recorder should print in accordance with what described in the Operation Manual.

5.1.5 Clock Test

Verify the accuracy of clock counting when conducting the system test, and then set the clock to the current time.

5.1.6 Whole Parameter Test

Plug all monitoring parameters and monitor them one by one. During the simultaneous monitoring of all parameters, the parameters should not interfere with each other.

5.1.7 Set Defaults at the time of loading Software

Perform such main menu operations as patient information management, trend data review, system setup, etc. The system responds correctly and no obvious error occurs during functioning. Each function meets the product requirements.

5.2 Material List

1	6006-20-39350	Handle cap
2	6006-20-39351	Rear housing
3	6006-30-39352	Main board
4	6006-20-39353A	PCB board for main board
5	6006-30-39354	Keypad
6	6006-20-39355A	PCB board for keypad
7	6006-20-39358	Front housing
8	6006-20-39359	Battery door
9	6006-20-39360	NIBP parameter connector cap
10	6006-20-39361	Alarm light cover
11	6006-20-39362	Temperature module cap (No

		temperature)
12	6006-20-39366	SpO2 mount bracket
13	6006-20-39367	Master bracket (lead-acid)
14	6006-20-39368	NIBP bracket
15	6006-20-39369	Recorder bracket
16	6006-20-39370	Serial port bracket
17	6006-20-39372	Silicon button
18	6006-20-39373	Fan bracket
19	6006-20-39374	Machine label (Chinese)
20	6006-20-39375	Foot cushion
21	6006-20-39376	Battery door connection bond
22	6006-20-39378	SPO2 parameter connector cap
23	6006-20-39379	Speaker press plate
24	6006-20-39380	Main board power cord
25	6006-20-39381	Recorder signal line
26	6006-20-39382	SpO2 module connection cables
27	6006-20-39383	Keypad signal line
28	6006-20-39384	LCD signal line
29	6006-21-39385	Speaker and connection cables
30	6006-21-39386	Power board AC input connection cables
31	6006-20-39387	Fan and connection cables
32	6006-20-39388	Power board-to-battery back-plate connection cables (lithium)
33	6006-20-39389	Power board-to-battery back-plate connection cables (lead-acid)
34	6006-21-39390	SPO2 signal line (Mindray)
35	6006-21-39391	SPO2 signal line (MASIMO)
36	6006-21-39392	SPO2 signal line (NELLCOR)
37	6006-30-39393	Power board (lithium)
38	6006-20-39394A	PCB board for power board
39	6006-30-39399	12V DC/DC board
40	6006-20-39400A	PCB board for 12V DC/DC board
41	6006-30-39401	Master bracket assembly (lead-acid)
42	6006-30-39402	Master bracket assembly (lithium)
43	6006-30-39403	Main unit (lead-acid/SpO2 only)
44	6006-30-39404	Main unit (lithium/SpO2 only)
45	6006-30-39405	Main unit (lead-acid/NIBP)
46	6006-30-39406	Main unit (lithium/NIBP)
47	6006-30-39407	Main unit (lead-acid/ overpressure mode)
48	6006-30-39408	Main unit (lithium/overpressure mode)
49	6006-20-39413	Master transformer
50	6006-20-39414	3.3V DC/DC inductor

51	6006-20-39415	Silicon power button
52	6006-20-39416	Master bracket (lithium)
53	6006-20-39417	Lithium battery fixed bracket
54	6006-20-39418	Speaker press plate
55	6006-20-39419	Lead-acid battery fixed bracket
56	6006-20-39420	Overlay of front housing (English)
57	6006-20-39421	Overlay of external interface
58	6006-20-39422	Heat sink for switching tube
59	6006-20-39423	Heat sink for rectifier tube
60	6006-20-39424	Heat sink for charging switch tube
61	6006-30-39427	Lithium battery socket board
62	6006-20-39428A	PCB board of lithium battery socket
63	6006-20-39429	Overly of front housing (Chinese)
64	6006-20-39431	Silicon keypad press plate
65	6006-20-39432	Bolster plate for middle LED (bottom)
66	6006-20-39433	Bolster plate for small LED (right)
67	6006-20-39434	Fan press plate
68	6006-20-39435	Recorder cap
69	6006-20-39436	VS-800 Operation Manual (Chinese)
70	6006-20-39437	VS-800 Operation Manual (English)
71	6006-20-39438	VS-800 Maintenance Manual (Chinese)
72	6006-20-39439	VS-800 Maintenance Manual (English)
73	6006-20-39440	VS-800 Operation Card (Chinese)
74	6006-20-39441	VS-800 Operation Card (English)
75	6006-20-39442	Operation Manual (Chinese/OEM)
76	6006-20-39443	Operation Manual (English/OEM)
77	6006-20-39444	Maintenance Manual (Chinese/OEM)
78	6006-20-39445	Maintenance Manual (English/OEM)
79	6006-30-39446	Front housing assembly
80	6006-30-39447	Rear housing assembly
81	6006-30-39448	Lead-acid battery assembly
82	6006-30-39449	Lithium battery assembly
83	6006-20-39450	Insulating plate for keypad
84	6006-20-39451	Insulating plate for main board
85	6006-20-39453	Machine label (Chinese/bearing CE mark)
86	6006-20-39454	Machine label (European)
87	6006-20-39455	Machine label (FDA)
88	6006-20-39456	SN bar code label
89	6006-20-39457	Outside label (domestic)
90	6006-20-39458	Outside label (European)
91	6006-20-39459	Outside label (FDA)
92	6006-20-39460	VS-800 certificate

93	6006-20-39461	Upper foam
94	6006-20-39462	Lower foam
95	6006-20-39464	Insulating plate for power board
96	6006-20-39465	Overlay of front housing (Chinese /SpO2 only)
97	6006-20-39466	Overlay of front housing (English /SpO2 only)
98	6006-30-39467	Front housing assembly (SpO2 only)
99	6006-30-39468	Packaging material
100	6006-30-39469	NIBP module package
101	6006-30-39470	SPO2 module package (MINDRAY)
102	6006-30-39471	SPO2 module package (MASIMO)
103	6006-30-39472	SPO2 module package (NELLCOR)
104	6006-30-39473	Label package (domestic)
105	6006-30-39474	Label package (international)
106	6006-30-39475	Label package (FDA)
107	6006-30-39476	System software (online downloading)
108	6006-30-39477	Keypad (SpO2 only)
109	6006-30-39478	Power board (lead-acid)
110	6006-20-39480	12V DC/DC inductor
111	6006-20-39482	LED anti-dazzling screen
112	6006-20-39483	Washer of NIBP nozzle
113	6006-20-39484	Washer of grounding connector
114	6006-20-39485	Torsional spring for button battery
115	6006-20-39486	Fastening screw for button battery
116	6006-20-39487	Housing dust-proof bar 1
117	6006-20-39488	Housing dust-proof bar 2
118	6006-30-39489	Main board test software
119	6006-30-39490	Guide software
120	6006-30-39491	PC browse software for data exporting
121	6006-20-39492	Recorder power cord
122	6006-20-39493	Keypad power connection cables
123	6006-20-39494	NIBP module connection cables
124	6006-30-39495	FPGA configuration code
125	6006-30-39496	CPLD configuration code
126	6006-20-39502	LCD backplate
127	6006-30-39503	Label package (for domestic bid)
128	6006-20-39504	Alarm Overlay
129	6006-20-39509	Overlay of NIBP bracket
130	6006-20-39510	VS-800 CD label（english）
131	6006-20-39511	VS-800 CD label（english）
132	6006-20-39512	Insulating plate(lithium) for keypad

133	6006-20-39513	external packing box
134	6006-30-39514	CD assembly（chinese）
135	6006-30-39515	CD assembly（English）
136	6006-30-39516	Front housing assembly（maintain）
137	6006-30-39517	Front housing assembly （single SPO2/ maintain）
138	6006-30-39518	Rear housing assembly（maintain）
139	6006-20-39520	Waterproof bar

5.3 NIBP Calibration Method

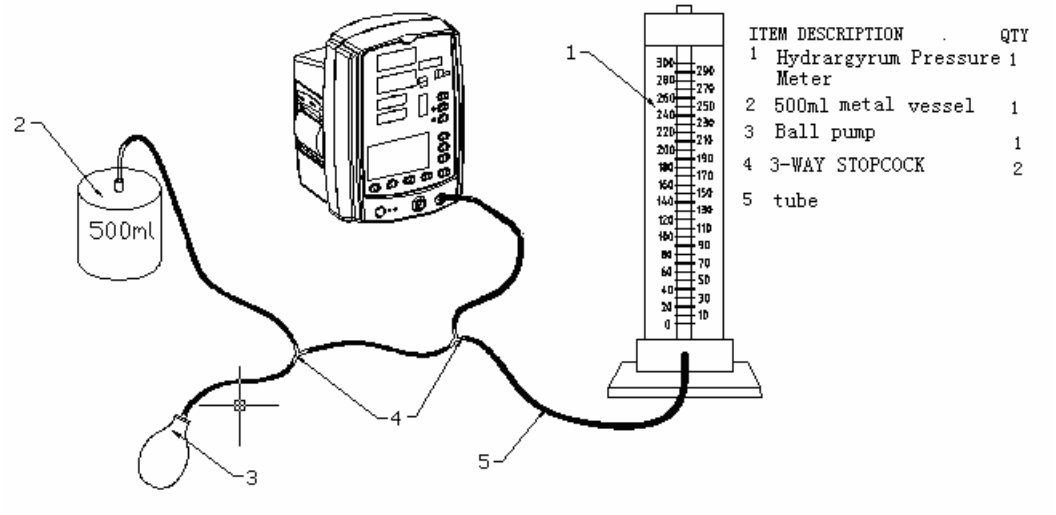

Figure 1 NIBP Static Pressure Calibration Method

Calibration method: Increase the pressure at intervals of 50mmHg(6.7kPa). The maximum difference between the monitor and calibrator at any pressure point within the measurement range does not exceed ±3mmHg (±0.4kPa). Similarly, when decreasing the pressure, the difference between the monitor and calibrator at any pressure point within the measurement range should not exceed±3mmHg (±0.4kPa).

Chanpter6 Maintenance and Cleaning

6.1 Inspection

6.1.1 Inspection before Using the Monitor

Before using the monitor, check:

1. The monitor for mechanical damages;
2. All exposed wires, male connectors and accessories;
3. All functions that may be used on patients, thus guaranteeing the good performance of the monitor.

In case of any indication of functional damage, stop using the monitor, and contact bio-medical engineers of the hospital or Mindray service engineers immediately.

6.1.2 Routine Inspection

An overall inspection, including the functional safety inspection, must be performed on the monitor by qualified personnel for every 6-12 months or after maintenance each time. All inspections must be performed by qualified service personnel when it is necessary to disassemble the monitor.

⚠Warning⚠

Failure on the part of the responsible hospital or institution employing the monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazard.

6.2 General Cleaning

⚠Warning⚠

Be sure to shut down the system and disconnect all power cords from the outlet before cleaning the equipment or accessories.

The VS-800 Vital Signs Monitor should be free from dust.

The exterior surface and LCD should be cleaned with non-corrosive cleaning solutions, such as the diluted soap water and water.

⚠ **Warning**⚠

To avoid damages to the VS-800 Vital Signs Monitor:

- ALWAYS dilute the solutions according to the manufacturer's suggestions;
- ALWAYS wipe off all the excess cleaning solution with a dry cloth after cleaning;
- NEVER submerge the equipment into water or any cleaning solution, or pour or spray water or any cleaning solution on the equipment;
- NEVER permit fluids run into the casing, switches, connectors, or any ventilation openings in the equipment;
- NEVER use abrasive or erosive cleaners of any kind as well as cleaners containing acetone.

6.3 Cleaning Solutions

Following are examples of cleaning solutions:

- Diluted soap water
- Diluted ammonia water
- Diluted sodium hyoichlo (bleaching agent)
- Diluted formaldehyde (35 to 37%)
- Hydrogen peroxide (3%)
- Ethanol (70%), or Isopropanol (70%)

6.4 Sterilization

Sterilization may cause damage to the equipment; therefore, only the sterilization that is considered necessary as per the hospital's service plan is recommended. Before sterilizing the equipment, clean it first.

Recommended sterilization materials: Ethanol 70%, Isopropanol 70%), and aldehyde based.

For the sterilization materials for NIBP cuffs, refer to relevant chapter in *VS-800 Operation Manual*.

6.5 Disinfection

Disinfection may cause damage to the equipment; therefore, only the disinfection that is considered necessary as per the hospital's service plan is recommended. Before disinfecting the equipment, clean it first.

For the disinfections of SpO_2 sensors and NIBP cuffs, refer to relevant chapters in *VS-800 Operation Manual*.

6.6 Contact Information for Maintenance and Technical Support

Address	**Mindray Building, Keji 12th Road South, Hi-Tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China**
Manufacturer	**Customer Service, Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Post Code	**518057**
Tel	**0755--26582888**
Fax	**0755--26582680**
Free Hotline	**800 830 3312**
Website	**http://www.mindray.com.cn/**
E-mail	**customerservice@mindray.com.cn**

FOR YOUR NOTES